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Contents

Federal Register

Vol. 89, No. 79

Tuesday, April 23, 2024

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

10728.....30257

12 CFR

1091.....30259

14 CFR

Proposed Rules:

39 (4 documents) 30281, 30284, 30286, 30289

71.....30292

16 CFR

Proposed Rules:

1112 (2 documents) 30294, 30295

1130 (2 documents) 30294, 30295

1242.....30294

1243.....30295

22 CFR

62.....30268

24 CFR

5.....30272

50.....30850

55.....30850

58.....30850

200.....30850

202.....30272

32 CFR

Proposed Rules:

246.....30296

33 CFR

Proposed Rules:

110.....30299

40 CFR

180.....30277

42 CFR

417.....30448

422.....30448

423.....30448

460.....30448

43 CFR

3000.....30916

3100.....30916

3110.....30916

3120.....30916

3130.....30916

3140.....30916

3150.....30916

3160.....30916

3170.....30916

3180.....30916

47 CFR

Proposed Rules:

64.....30303

50 CFR

Proposed Rules:

17.....30311

660.....30314

679.....30318

Federal Register
Vol. 89, No. 79
Tuesday, April 23, 2024

Presidential Documents

Title 3—

The President

Proclamation 10728 of April 18, 2024

Education and Sharing Day, USA, 2024

By the President of the United States of America

A Proclamation

This Education and Sharing Day, USA, we remember the life and legacy of the Lubavitcher Rebbe, Rabbi Menachem Mendel Schneerson, as the leader of the Chabad-Lubavitch movement and recommit to our shared values of honesty, dignity, and equal justice that he long championed and that have made America strong.

Forced to flee Nazi-occupied Europe during one of history's darkest moments, the Rebbe found a new home and purpose in America. In the wake of the Holocaust, he led hundreds of thousands to deepen their faith. As a prolific scholar and teacher, his calls for new schools and community centers inspired people to build them in all 50 States and across the globe, and they moved generations to embrace education not only as a means of self-improvement but as an essential path to a more just society. Here in America, he also offered counsel to some of my predecessors as President, always advocating for our Nation's role as a beacon of hope in the world.

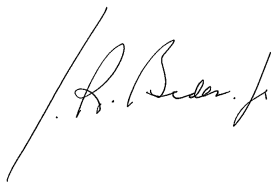
We honor the Rebbe's birthday every year, but we know this year is different. Violence and cruelty have reminded us that hate never goes away—it only hides. Silence is complicity, and America will not be silent. As Americans, we reject terrorism and will keep working unequivocally to combat anti-semitism at every turn. My Administration remains dedicated to Israel's security, and here at home, we have been implementing America's first-ever National Strategy to Counter Antisemitism. We will give hate no safe harbor.

The Rebbe knew that education is fundamental to cultivating understanding and acceptance. It opens us up to one another, and it builds not just knowledge but character, as well as an awareness of something bigger than ourselves. The Rebbe's beliefs are reflected in the American creed that every person is created equal and deserves to be treated equally throughout their lives, starting with access to a quality education—a mission my Administration shares.

As we approach the 30th anniversary of the Rebbe's passing, we honor his work by celebrating our common faith in our Nation and by working to ensure that every American has a chance to learn, grow, and thrive—in the classroom and as caring and courageous people.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 19, 2024, as Education and Sharing Day, USA. I call upon government officials, educators, volunteers, and all the people of the United States to observe this day with appropriate programs, ceremonies, and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this eighteenth day of April, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



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Rules and Regulations

Federal Register
Vol. 89, No. 79
Tuesday, April 23, 2024

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1091

[Docket No. CFPB–2024–0006]

Procedures for Supervisory Designation Proceedings

AGENCY: Consumer Financial Protection Bureau.

ACTION: Final rule; request for public comment.

SUMMARY: The Consumer Financial Protection Bureau (CFPB or Bureau) is updating the CFPB's procedures for designating nonbank covered persons for supervision, to conform to a recent organizational change and to further ensure that proceedings are fair, effective, and efficient for all parties.

DATES: This rule is effective on April 23, 2024. Comments must be received on or before May 23, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CFPB–2024–0006, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. A brief summary of this document will be available at *https://www.regulations.gov/docket/CFPB-2024-0006.*
- *Email: 2024-SupervisoryDesignationProceedings@cfpb.gov.* Include Docket No. CFPB–2024–0006 in the subject line of the message.
- *Mail/Hand Delivery/Courier:* Comment Intake—Procedures for Supervisory Designation Proceedings, c/o Legal Division Docket Manager, Consumer Financial Protection Bureau, 1700 G Street NW, Washington, DC 20552.

Instructions: The CFPB encourages the early submission of comments. All submissions should include the agency name and docket number for this rule. Commenters are encouraged to submit comments electronically. In general, all comments received will be posted without change to *https://www.regulations.gov.*

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Proprietary information or sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: George Karithanom, Regulatory Implementation & Guidance Program Analyst, Office of Regulations, at 202–435–7700 or *https://reginquiries.consumerfinance.gov/.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Consumer Financial Protection Act of 2010 (CFPA) establishes the CFPB as an independent bureau in the Federal Reserve System and assigns the CFPB a range of rulemaking, enforcement, supervision, and other authorities.[1]

One of the supervisory authorities under the CFPA is section 1024(a)(1)(C). It authorizes the CFPB to supervise a nonbank covered person that the CFPB ''has reasonable cause to determine, by order, after notice to the covered person and a reasonable opportunity for such covered person to respond . . . is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.'' [2] In 2013, the CFPB issued procedures to govern these supervisory designation proceedings (2013 rule).[3] However, the authority was largely unused for a number of years.[4] In 2022, the CFPB announced that it would begin to make active use of the supervisory designation authority, and it made a limited amendment to the procedures to establish a specific process for public release of final decisions and orders (2022 rule).[5]

The CFPB has initiated a number of supervisory designation proceedings since the 2022 rule. On February 23, 2024, the CFPB publicly released the first decision and order in a contested proceeding, which discusses the CFPB's view of the section 1024(a)(1)(C) authority.[6] Other institutions have consented to CFPB supervision, in some cases without a proceeding and in other cases during a proceeding. The CFPB looks forward to a productive supervisory relationship with all the institutions that are now within its supervisory authority.

In late February 2024, the CFPB began a transition to a new organizational structure for its supervision and enforcement work. The functions of the Associate Director of the Division of Supervision, Enforcement, and Fair Lending are being transferred to the Supervision Director as head of a Division of Supervision and the Enforcement Director as head of a Division of Enforcement. This rule is in part intended to implement that change in the context of supervisory designation proceedings.

Legal Authority

Section 1024(b)(7) of the CFPA authorizes the CFPB to ''prescribe rules to facilitate supervision'' of the nonbank covered persons described in section 1024(a), as well as to facilitate ''assessment and detection of risks to consumers.'' [7] Additionally, section 1022(b)(1) provides, in relevant part, that the CFPB Director ''may prescribe rules . . . as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.'' [8] The CFPB issues this rule based on its authority under section 1024(b)(7) and section 1022(b)(1).

[1] Public Law 111–203, title X, 124 Stat. 1376, 1955–2113 (2010).

[2] 12 U.S.C. 5514(a)(1)(C). The Bureau must base such reasonable-cause determinations on complaints collected by the Bureau under 12 U.S.C. 5493(b)(3), or on information collected from other sources. *Id.*

[3] 78 FR 40352 (July 3, 2013); *see also* 85 FR 75194 (Nov. 24, 2020) (updating certain cross-references).

[4] The CFPB did, from time to time, issue enforcement consent orders that included the entity's consent to supervision.

[5] 87 FR 70703 (Nov. 21, 2022); *see also* 87 FR 25397 (Apr. 29, 2022).

[6] *World Acceptance Corp.,* File No. 2023–CFPB–SUP–0001 (Nov. 30, 2023), *available at https://www.consumerfinance.gov/compliance/supervision-examinations/institutions/.*

[7] 12 U.S.C. 5514(b)(7).

[8] 12 U.S.C. 5512(b)(1).

Discussion

Subpart A—General

1091.101 Definitions.

The rule makes technical changes to definitions.

Subpart B—Determination and Voluntary Consent Procedures

1091.201 Voluntary consent to supervisory authority.[9]

The initiating official and respondents have resolved the large majority of proceedings by consent. Under the 2013 rule, there were two provisions that established separate procedural avenues for entering into a consent agreements. One provision (former § 1091.103(b)) required the initiating official to enclose a proposed consent agreement with the Notice of Reasonable Cause (Notice), and the other provision (former § 1091.110) authorized consent agreements to be agreed at any time. There were small differences between the two provisions.

Under this rule, a proposed consent agreement will continue to be enclosed with the Notice, and consent agreements can also be agreed at any other time. However, the Bureau is combining the two previous provisions into one provision (§ 1091.201) and harmonizing their differences, in order to reduce complexity and risk of confusion. One of the two previous provisions stated that the consent agreement does not constitute an admission by the respondent, while the other did not address that point expressly; new § 1091.201 clarifies that a consent agreement does not constitute an admission. One of the two previous provisions contemplated a two-year period for supervision while the other allowed duration to be addressed on a case-by-case basis; new § 1091.201 takes the latter course. All consent agreements under both previous provisions were for two years, and the CFPB anticipates that will continue to be the typical duration. But addressing duration on a case-by-case basis rather than by rule will provide flexibility if a longer or shorter period were hypothetically warranted.

1091.202 Notice of Reasonable Cause.[10]

The Supervision Director as initiating official commences a contested proceeding by serving the respondent with a Notice of Reasonable Cause (Notice). The Notice is the ordinary means by which the CFPB provides notice under section 1024(a)(1)(C) of the CFPA, although there may sometimes be proceedings in which additional notice is provided at later points in the proceeding, for example through supplemental briefing.

Paragraph (c) simplifies certain general background information about the section 1024(a)(1)(C) process that was included in the Notice under the 2013 rule.

Paragraph (d) includes an update to the method for serving the Notice. The 2013 rule included methods of service that were patterned on how a notice of charges is served under the Rules of Practice for Adjudication Proceedings.[11] In order to provide an additional measure of flexibility, this rule also permits other methods that are ''reasonably calculated to give notice.''

Paragraph (e) codifies that the initiating official may withdraw a Notice. The 2013 rule did not expressly address this subject.

1091.203 Response.[12]

This provision governs the response, which is the respondent's opportunity to respond to the Notice. The rule makes minor technical changes to the provision.

1091.204 Reply by initiating official.

This new provision provides the initiating official with the option of filing a written reply to the response. Under the 2013 rule, there was no such reply. Because of the initiating official's role in formulating the Notice, the initiating official will likely have observations that are useful to the Director in considering the response.

1091.205 Supplemental oral response.[13]

This provision governs a supplemental oral response before the Director, which a respondent can request in its response under § 1091.203. Under the 2013 rule, a respondent presented the supplemental oral response to the Associate Director for Supervision, Enforcement, and Fair Lending. However, as discussed in connection with § 1091.206 below, in light of the elimination of the Associate Director position, the rule merges the Associate Director's and Director's adjudicative roles.[14] The rule also gives the Director more flexibility regarding whether a supplemental oral response is in person at the Bureau's headquarters, by telephone, or by video conference, consistent with ongoing changes to working practices and possible future public health needs.[15]

1091.206 Determination by the Director.[16]

After the Notice, response, reply (if any), and supplemental oral response (if any), the rule provides for the Director to make a final determination in a proceeding.

Under the 2013 rule, the Associate Director of the Division of Supervision, Enforcement, and Fair Lending submitted a recommended determination to the Director, and then the Director issued a final determination. But as noted above, the role of Associate Director will no longer exist under the new organizational structure. The Associate Director's supervision-related functions are being transferred to the Supervision Director, who serves as initiating official in the context of supervisory designation proceedings. Accordingly, this rule merges the adjudicative roles of the Associate Director and Director in these proceedings. This change, in addition to aligning with the new organizational structure, will make proceedings more efficient. The former two-stage process resulted in a more complex and resource-intensive process and a longer timeline for resolving proceedings. Merging the adjudicative roles of Associate Director and Director does not diminish any of the respondent's opportunities to express its views to the Bureau, but merely streamlines the Bureau's internal decision-making process after those views are expressed.

Paragraph (b) codifies the fact that the Director may sometimes request supplemental briefing before making a final determination, which is consistent with the 2013 rule but was not expressly discussed in the 2013 rule.

Paragraph (d) requires a separation of functions between Bureau employees who advise the Director in the Director's adjudicative role on the one hand and Bureau employees who advise the initiating official on the other. This separation is not required by the Administrative Procedure Act, but the Bureau maintains it as a matter of policy. The 2013 rule included a similar separation of functions at the Director level, although at the Associate Director level it did not mandate a separation between the Associate Director's advisers and initiating official's advisers.

[9] Formerly §§ 1091.103(b) and 1091.110.

[10] Formerly §§ 1091.102 to 1091.104.

[11] *See* 12 CFR 1081.113(d)(1).

[12] Formerly § 1091.105.

[13] Formerly § 1091.106.

[14] Because the existing definition of the term Director under § 1091.101 includes a designee of the Director, there might be circumstances where the Director delegates the responsibility for being present at a supplemental oral response to a designee.

[15] *See also* § 1091.203(b)(3).

[16] Formerly § 1091.109.

Subpart C—Post-Determination Procedures

1091.301 Petition for termination of order.[17]

This provision governs petitions by respondents to terminate an existing order. The rule makes technical changes to conform to changes elsewhere in the procedures. It also codifies the fact that the Director might sometimes request supplemental briefing, similar to § 1091.206(b).

Subpart D—Miscellaneous Provisions

1091.401 Methods of filing and serving documents.[18]

The rule clarifies the method of filing and serving documents, which will generally be by email. The service of the Notice at the start of a proceeding, when a respondent's email address may not be known, is governed by a specific rule under § 1091.202(d).

1091.402 Time limits.[19]

The rule simplifies the former method for calculating time limits under the 2013 rule, which varied by delivery channel to allow additional time for mail or delivery services to arrive. This complexity has generated confusion for some respondents and is no longer warranted because email is generally instantaneous.

1091.403 Word limits.

The rule introduces a word limit for the Notice, response, and certain other key filings, based on Federal Rules of Appellate Procedure 32(a)(7)(B) and 32(f). Relatedly, it introduces a certification of word count based on Federal Rule of Appellate Procedure 32(g). In past proceedings, some parties' outside counsel submitted very lengthy filings in the absence of any page or word limit. Like any word limit, the CFPB intends the new limit to help focus arguments and mitigate expense for all participants.

1091.404 Changes to methods of filing and service, time limits, and word limits.[20]

This provision governs changes to the methods set out in §§ 1091.401 to 1091.403. In the case of changes to time limits or word limits, the provision notes that they are disfavored. Under the provision, a change can be approved in one of three ways: by consent of the initiating official and the respondent, with notice to the Director; by written request to the Director; or upon the Director's own motion. The possibility of changes by consent is intended to avoid the need for the Director to become involved in minor issues that are not controversial between the initiating official and the respondent. However, the provision states that the Director can direct otherwise. There may also be circumstances where the initiating official believes that a potential change warrants a decision by the Director through a written request and so withholds consent, even if the initiating official does not oppose the change.

1091.405 Confidentiality of proceedings.[21]

The 2022 rule created a process for the CFPB to publicly release final decisions and orders. This rule maintains the 2022 rule's approach, although it clarifies that consent agreements entered into by the initiating official and respondent under § 1091.201 are not subject to the public release process. These agreements are generally short formal documents without reasoning that is significant or could form the basis for precedent. Relatedly, the CFPB notes that an order entered as provided in § 1091.206(a)(1), because a respondent has failed to file a response and so has defaulted under § 1091.203(c), would typically not have content that warrants public release. However, such orders are subject to the process under § 1091.405 for considering public release, because of the possibility that some may include reasoning that warrants public release.

1091.406 Multiple respondents.

The rule clarifies that multiple respondents might be named in a Notice, as well as clarifying the process for adding an additional respondent or respondents to a pending proceeding. Including multiple respondents in one proceeding—for example, business partners—may, in appropriate cases, avoid the delay and inefficiency of serial proceedings and also would allow the Bureau to consider related issues at once.[22]

1091.408 Issue exhaustion.[23]

The Supreme Court has explained that: ''Administrative review schemes commonly require parties to give the agency an opportunity to address an issue before seeking judicial review of that question.'' [24] New § 1091.408 is an express issue exhaustion provision that parallels § 1081.408 of the Rules of Practice for Adjudication Proceedings. The CFPB is adopting it for the same reasons that the CFPB explained in the context of the Rules of Practice.[25] The new issue exhaustion provision is generally similar to former § 1091.105(d), which was titled ''Waiver,'' together with principles of administrative law that would apply in the absence of an express issue exhaustion provision.

Effective Date and Transitional Arrangements

This rule is effective upon **Federal Register** publication. It applies to proceedings initiated on or after the effective date. It also applies to proceedings that are pending on the effective date, except to the extent the Director determines that is not just or practicable.[26]

Section 1022(b)(2) Analysis

In developing this rule, the Bureau has considered its benefits, costs, and impacts in a manner consistent with section 1022(b)(2)(A) of the CFPA.[27] In addition, the Bureau has consulted with the prudential regulators and the Federal Trade Commission, including regarding consistency of the rule with any prudential, market, or systemic objectives administered by those agencies, in a manner consistent with section 1022(b)(2)(B) of the CFPA.[28]

Among other sources of supervisory authority, the Bureau can supervise a nonbank covered person that the Bureau ''has a reasonable cause to determine, by order, after notice to the covered person and a reasonable opportunity for such covered person to respond . . . is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.'' [29] The Bureau established a rule to implement a procedure to fulfil this statutory authority in 2013 (2013 rule) and amended this rule in 2022 (2022 rule). The Bureau is issuing this

[17] Formerly § 1091.113.

[18] Formerly § 1091.107.

[19] Formerly § 1091.114.

[20] Formerly § 1091.115(a) and (b).

[21] Formerly § 1091.115(c).

[22] Because additional respondents might be added to a proceeding at any stage, the provision gives the Director flexibility to decide what process is appropriate in order to provide the additional respondents a reasonable opportunity to respond to the supplemental Notice.

[23] Formerly § 1091.105(d).

[24] *Carr* v. *Saul,* 141 S. Ct. 1352, 1358 (2021).

[25] *See* 88 FR 18382, 18387–88 (Mar. 29, 2023) (discussing 12 CFR 1081.408).

[26] The CFPB notes the Supreme Court commonly applies rule changes, ''insofar as just and practicable,'' to pending proceedings in Federal courts. *E.g.,* 344 FRD. 850, 851 (U.S. 2023); 340 FRD. 810, 811 (U.S. 2022); 337 FRD. 813, 814 (U.S. 2021). The CFPB also notes that the above transitional arrangements, although not codified, form an operative part of the rule.

[27] 12 U.S.C. 5512(b)(2)(A).

[28] 12 U.S.C. 5512(b)(2)(B). Whether section 1022(b)(2)(A) and section 1022(b)(2)(B) are applicable to this rule is unclear, but in order to inform the rulemaking more fully the Bureau performed the described analysis and consultations.

[29] 12 U.S.C. 5514(a)(1)(C). The Bureau must base such reasonable-cause determinations on complaints collected by the Bureau under 12 U.S.C. 5493(b)(3), or on information collected from other sources. *Id.*

final rule to amend the procedures governing the CFPB's supervisory designation proceedings.

A. Data Limitations and Quantification of Benefits, Costs, and Impacts

The data are generally limited with which to quantify potential costs, benefits, and impacts of the rule's provisions. The CFPB has conducted a limited number of supervisory designation proceedings under the prior 2013 and 2022 rules, but the CFPB does not have quantitative data regarding the costs to respondents or other impacts of those proceedings. The CFPB also does not have quantitative data to predict the impacts of the changes made by this rule relative to the prior legal and procedural framework, which is the comparison that is relevant for this analysis.

In light of these data limitations, the analysis below generally provides a qualitative discussion of the benefits, costs and impacts of the rule. General economic principles and the Bureau's experience and expertise in consumer financial markets, together with the limited data that are available, provide insight into these benefits, costs, and impacts.

B. Baseline for Analysis

In evaluating the rule's benefits, costs, and impacts of the rule, the CFPB considers the impacts against a baseline that includes the legal and procedural framework regarding supervisory designation proceedings for nonbank covered persons that existed before the issuance of the rule. Therefore, the baseline for the analysis of the rule includes separate adjudicative roles for the Director and the Associate Director for Supervision, Enforcement, and Fair Lending—that is, the statutory baseline implemented by the 2013 rule as amended by the 2022 rule.

C. Potential Benefits and Costs to Consumers and Covered Persons

The rule would apply to covered persons as defined in the CFPA, which are generally persons that engage in offering or providing a consumer financial product or service.[30] Relative to the statutory baseline, this rule implements several changes that the Bureau believes streamlines and improves transparency in the decision-making process, and clarifies the rights of nonbank covered entities subject to this rule. Notably, this rule eliminates the role of the Associate Director in filing a recommendation prior to the Director's final determination and instead assigns the Director to receive responses, including optional supplementary oral responses, in order to make a final determination. Furthermore, it clarifies the process by which persons may enter consent agreements with the Bureau, among other procedural changes. Overall, the Bureau believes these changes will not diminish the rights of respondents to reply to a Notice of Reasonable Cause, do not impose significant costs relative to the statutory baseline, increase transparency in the decision-making process, and clarify the processes by which covered persons may either respond or enter into a consent agreement with the Bureau.

The rule eliminates the role of the Associate Director in making a recommendation to the Director. This reflects a broader organizational structural change at the CFPB that eliminates the position of Associate Director of Supervision, Enforcement, and Fair Lending. Relative to the baseline, the rule makes no changes to the rights to respond by nonbank covered entities, maintains separation of roles between the initiating official and decisional employees in the determination process, maintains the requirement that the Director include the basis for their decision in their final determination, and should reduce the amount of time on net between service of the Notice and the final determination.[31] The rule also codifies the ability for the Director to request additional briefing from the respondent, the initiating official, or both. Because there is no reduction in the ability of nonbank covered entities to respond to the Notice and access information constituting the basis for the Director's determination, there are no additional costs imposed on nonbank covered entities. Furthermore, the Bureau believes the reduction in time and general streamlining of the decisional process will benefit nonbank covered entities by improving the efficiency of this rule's application.

The rule allows for the initiating official to reply to the respondent's response to the Notice. The Bureau believes this may benefit respondents by allowing for more transparency in the determination process. The 2013 rule did not allow for the initiating official to respond to the written reply but did allow for the initiating official to participate in the optional supplementary oral response. Moreover, the 2013 rule did not preclude the initiating official from advising the Associate Director in drafting their recommendation. By allowing for a reply by the initiating official to the respondent's written response, the Bureau believes respondents could gain more insight into the decisional process which could then be incorporated into an optional supplementary oral response.

The rule also sets out changes in the process by which a person may voluntarily consent to the Bureau's supervisory authority. Specifically, the rule consolidates two previous provisions regarding consent agreements. Under one provision of the 2013 rule, a respondent could respond to a Notice by signing an enclosed consent agreement that led to the respondent being supervised for two years. Under a separate provision, the respondent and the Bureau could enter into a consent agreement at any time, with a duration to be determined by case-by-case negotiation. Under the new rule, a proposed consent agreement will continue to be enclosed with the Notice and an agreement can also be reached at any other time, but the rule will no longer mandate a two-year period in the former case.

Relative to the baseline, the removal of the default option of a two-year consent agreement, to be replaced with the option for a consent agreement with a negotiated length of time, may impose additional costs on covered entities subject to this rule. However, the Bureau believes several factors limit the expected realized costs of this change. First, as mentioned above, the Bureau has conducted a limited number of supervisory designation proceedings under this authority. The Bureau anticipates it will continue to conduct a limited number of proceedings relative to the size of the market of covered entities subject to this rule. Second, based on prior experience and expertise, the Bureau anticipates that the majority of consent agreements will continue to last for a period of two years. Third, in a case where the complexity or severity of potential consumer risks merits a supervisory relationship longer than two years in the initiating official's assessment, there are other features of the rule that limit any additional realized costs relative to baseline on the covered entity, notably the option to contest the Notice and the ability for the Bureau to issue a new Notice at the end

[30] For the full scope of the term ''covered person,'' *see* 12 U.S.C. 5481(6).

[31] The length of time that the Director has to make a final determination is increased relative to baseline; however, the elimination of the role of the Associate Director and streamlining of the decisional process reduces the total amount of time between Notice and determination.

of the initial two-year order under the baseline.[32]

There is a large population of firms potentially subject to this rule.[33] The Bureau does not currently have access to comprehensive data on the number of nonbank covered persons subject to supervisory authority. To establish an estimate of the population of nonbank covered entities potentially subject to this rule, the Bureau uses the latest Economic Census publicly available data and North American Industry Classification System (NAICS) industry codes that align with financial services.[34] The Bureau estimates there are approximately 154,430 entities in these covered industries. It should also be noted that this estimate does not include other nonbank covered entities not categorized in one of the enumerated industries, *e.g.,* if consumer financial services are not their primary business activity. To date, the Bureau has exercised its supervisory authority under the 2013 and 2022 rules on fewer than a dozen covered entities and in any given year, and the Bureau anticipates exercising authority under this rule on the same number of entities. Hence, the Bureau believes the impact of this rule will be relatively limited, mitigating the realization of any potential costs associated with changes relative to baseline.

The majority of cases initiated under the 2013 rule have been settled by consent agreement and all past consent agreements have been for two years. The Bureau expects similar outcomes under this rule. However, the initiating official may assess that a longer period of time is necessary to maintain an effective supervisory relationship if a particular case is complex or poses severe risks to consumers.[35] In this case, a covered entity undergoing a supervisory proceeding under this rule may receive Notice with a proposed consent agreement lasting longer than two years.[36]

An order lasting longer than two years may pose additional costs relative to the baseline for the covered entity via additional supervisory activity. The Bureau has previously estimated the cost of compliance with supervisory activity based on reported average exam length and labor costs incurred by firms to participate in supervisory exams.[37] This calculation results in an estimate of approximately $27,000 in labor costs to comply with a supervisory examination. The Bureau recognizes that this estimate reflects national average labor costs and are thus subject to variability with respect to specific firms' realized costs. Furthermore, the Bureau recognizes that the staffing estimates are assessments for an average firm's needs and may also be subject to variability with respect to specific firms' requirements. The Bureau is open to public comments that provide additional data on estimates of staffing requirements and costs for compliance with supervisory activities.[38]

The Bureau anticipates that the majority of consent agreements under this rule will continue to be for two years, posing no significant additional costs on covered entities. The Bureau recognizes that for some entities undergoing supervisory activity under this rule, the complexity of the entity or the severity of consumer risk may result in a consent agreement lasting longer than two years, with each additional year imposing additional costs relative to baseline of approximately $27,000. In principle, it is possible that entities undergoing supervisory activity under this rule may enter into a consent agreement longer than three years; however, the Bureau anticipates this to be unlikely.

Finally, the Bureau notes that there are features of this rule and the statutory baseline that further limit any expected realized costs posed by the proposed rule. First, by their nature, consent agreements necessitate both parties' agreement to the order. A respondent may negotiate with the initiating official over the parameters of a consent agreement or may enter contested proceedings.[39] In general, entering into contested proceedings represents a cost on the respondent; however, insofar as there have been no substantive changes in the costs associated with entering contested proceedings relative to the baseline, the difference between these costs and the costs associated with the 2013 rule's provision to accept a two-year consent agreement represents an upper limit on the additional costs represented by this final rule relative to baseline.[40] Second, in cases where the

[32] As noted elsewhere in this analysis, the substantive costs associated with contested proceedings have not changed appreciably between the statutory baseline and the proposed rule. Hence, a covered entity issued Notice has the option to accept a negotiated consent agreement with potentially different costs relative to baseline or undergo contested proceedings with similar costs relative to baseline.

[33] The procedures established in the 2013 rule and this rule are only to assess whether a nonbank covered person will be made subject to the Bureau's supervisory authority based on a reasonable-cause determination. In general, there is no reason to make a determination under the 2013 rule or this rule with respect to a nonbank covered entity subject to the Bureau's supervisory authority under some other provision of section 1024(a) of the CFPA, 12 U.S.C. 5514(a). However, as discussed in the 2013 rule this is possible. Therefore, the Bureau does not exclude from coverage of the 2013 rule or this final rule nonbank covered entities that may be subject to supervision under a separate provision of section 1024(a).

[34] The relevant NAICS codes examined are 5222 (Nondepository credit intermediation); 5223 (Activities related to credit intermediation); 523920 (Portfolio management); 523930 (Investment advice); 532112 (Passenger car leasing); 532120 (Truck, utility trailer, and recreational vehicle rental and leasing); 5313 (Activities related to real estate); 561450 (Consumer reporting); and 561440 (Debt collection).

[35] In principle, an initiating official may assess that a shorter period of time is sufficient for a supervisory relationship. While the Bureau anticipates that this would be a rare occurrence given the Bureau's experience and expertise suggest that the minimum period of time to allow for an examination and follow-up is generally two years, this would likely lessen the costs associated with application of this rule on a nonbank covered entity.

[36] The respondent may otherwise understand that the Bureau and initiating official propose a consent agreement lasting longer than two years, *e.g.,* via other communications with the Bureau and initiating official.

[37] For an estimate of the length of examination, *see* Office of the Inspector General of the Board of Governors of the Federal Reserve System and the CFPB, ''The Bureau Can Improve Its Risk Assessment Framework for Prioritizing and Scheduling Examination Activities'' (Mar. 25, 2019) at 13, available at *https://oig.federalreserve.gov/reports/bureau-risk-assessment-framework-mar2019.pdf.*

[38] The Bureau has previously estimated the cost of compliance with supervisory activity based on reported average exam lengths, which would average one supervisory examination per year and require one-tenth of a full-time equivalent attorney and one full-time compliance officer. Furthermore, the Bureau estimates that supervisory examinations would last for 8 weeks on average, with an additional two weeks of preparation (supra note 38). Using the national average hourly labor cost of $84.84 for attorneys and $38.55 for compliance officers, the Bureau estimates that the direct labor costs for a supervisory examination would total approximately $19,000 (*See* U.S. Bureau of Labor Statistics, National Occupational Employment and Wage Estimates United States, May 2023, *https://www.bls.gov/oes/current/oes-nat.htm*). Assuming that wages represent approximately 70.4% of the total labor costs using the estimate of total compensation for private employees (See U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation: Private Industry Database, March 2024, *https://www.bls.gov/web/ecec/ecec-private-dataset.xlsx*), this results in an estimate of approximately $27,000 in labor costs to comply with a supervisory examination.

[39] Under the 2013 rule, there have been substantive communications between respondents and the Bureau prior to entering into any consent agreement, regardless under which provision of the 2013 rule the consent agreement was made. The Bureau anticipates that substantive communications will continue under this final rule and does not assess there to be significant changes in costs associated with these communications relative to baseline.

[40] A hypothetical firm that would contest the Notice under the 2013 rule would presumably continue to contest under this proposed final rule and incur no additional costs relative to baseline. A firm that would accept a two-year consent agreement under the 2013 rule but opt for contested proceedings under this rule would incur additional costs relative to baseline equivalent to the difference in costs between a contested proceeding and the two-year consent agreement. Hence, their

Continued

initiating official assesses that there is substantial complexity or severe consumer risks that merit supervisory activity beyond two years, under the statutory baseline a nonbank covered entity subject to application of the rule could opt for a two-year consent agreement; however, the Bureau could reissue a Notice at the end of this period, leading to additional costs associated with receipt, consideration, and reply to a fresh Notice. Under this final rule, the initiating official could propose a longer consent agreement that, subject to negotiation and acceptance of this consent agreement by the respondent, could avoid the potential need for another designation after two years and costs associated with receipt, consideration, and reply to a fresh Notice.

In summary, while the elimination of the two-year default option for consent agreement, to be replaced with the option for a consent agreement with negotiated length of time, may impose additional costs relative to baseline, the Bureau assesses these additional costs to be negligible. First, that the Bureau would be authorized to undertake supervisory activities with respect to a nonbank under this rule would not necessarily mean that the Bureau would in fact undertake such activities regarding that covered person in the near future. Rather, the supervision of any particular covered person as a result of this rule would be probabilistic in nature. Second, for a covered person undergoing supervisory activity under this rule, the Bureau anticipates the majority of cases will be settled by consent agreements lasting two years, imposing no additional costs. Third, for those entities where supervisory activity results in a proposed consent agreements lasting longer than two years, these potential realized costs are further mitigated by other features of the rule.[41]

The rule also makes certain other procedural changes to the processes for making and terminating designations, including: codifying the Director's authority to request supplemental briefing; imposing a word limit on key filings; clarifying procedures for filing and serving documents, with documents being generally filed and served by email; clarifying applicable procedures when there are multiple respondents; and codifying an issue exhaustion requirement that is generally similar to existing law. The rule further clarifies that the process for publicly releasing decisions and orders does not apply to consent agreements, because they lack sufficient content to serve as a precedent for future proceedings. The Bureau does not believe these changes impose significant additional costs onto nonbank covered persons relative to the baseline.

The rule will not have an impact on insured depository institutions or insured credit unions with $10 billion or less in assets as described in section 1026(a) of the CFPA.[42] Nor will the proposed rule have a unique impact on rural consumers.

Regulatory Matters

As a rule of agency organization, procedure, or practice, this rule is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act.[43] However, the Bureau is accepting comments on the rule.

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[44] Moreover, the Bureau's Director certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, an analysis is also not required on that basis.[45] This is for two independent reasons. First, the costs associated with the changes made by this rule relative to the baseline of the existing procedures are limited, as discussed above. Second, the number of entities that will be subject to the procedures is small, and within that group the number that would be small entities is likely to be either none or in the single digits each year, representing a very small fraction of small entities in the relevant consumer finance markets.

The Bureau has also determined that this rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[46]

Severability

If any provision of part 1091, or any application of a provision, is stayed or determined to be invalid, the remaining provisions or applications are severable and shall continue in effect.

List of Subjects in 12 CFR Part 1091

Administrative practice and procedure, Consumer protection, Credit, Trade practices.

Authority and Issuance

■ For the reasons set forth above, the Bureau revises 12 CFR part 1091 as set forth below:

PART 1091—PROCEDURES FOR SUPERVISORY DESIGNATION PROCEEDINGS

Subpart A—General

Sec.

Subpart B—Determination and Voluntary Consent Procedures

Sec.

Subpart C—Post-Determination Procedures

Sec.

Subpart D—Miscellaneous Provisions

Sec.

realized costs would be this difference. Similarly, a firm that would accept a two-year consent agreement under the 2013 rule and a possibly longer consent agreement under this final rule would incur additional costs relative to baseline equivalent to the difference between the costs associated with the consent agreement under this rule and those associated with the consent agreement under the 2013 rule. Moreover, the costs associated with a possibly longer consent agreement would be necessarily less than the costs of contested proceedings.

[41] The Bureau acknowledges that there are limitations in the estimates associated with relevant costs; however, with the estimates presented here, the Bureau believes the additional costs imposed on nonbank covered entities subject to this rule relative to baseline would be negligible (based on the limited number of supervisory activities the Bureau anticipates each year under this rule, the probabilistic nature that any particular entity would undergo supervisory activities under this rule, and the likelihood any supervisory activities would result in a consent agreement longer than two years).

[42] 12 U.S.C. 5516(a).

[43] 5 U.S.C. 553(b).

[44] 5 U.S.C. 603, 604.

[45] 5 U.S.C. 605(b).

[46] 44 U.S.C. 3501–3521.

PART 1091—PROCEDURES FOR SUPERVISORY DESIGNATION PROCEEDINGS

Authority: 12 U.S.C. 5512(b)(1), 5514(a)(1)(C), 5514(b)(7).

Subpart A—General

§ 1091.100 Scope and purpose.

This part sets forth procedures to implement section 1024(a)(1)(C) of the Consumer Financial Protection Act of 2010 (12 U.S.C. 5514(a)(1)(C)) and establishes rules to facilitate the Bureau's supervisory authority over certain nonbank covered persons pursuant to section 1024(b)(7) of the Act (12 U.S.C. 5514(b)(7)).

§ 1091.101 Definitions.

For the purposes of this part, the following definitions apply:

Bureau, consumer, consumer financial product or service, and covered person have the definitions in 12 U.S.C. 5481.

Decisional employee means an employee of the Bureau who has not engaged in assisting the initiating official in either determining whether to issue a Notice of Reasonable Cause, or presenting the initiating official's position in support of a Notice of Reasonable Cause, either in writing or in a supplemental oral response, to the Director.

Director means the Director of the Bureau or his or her designee. If there is no Director, the term means a person authorized to perform the functions of the Director under this part, or his or her designee. For purposes of when the Director receives, files, or serves documents, the Director includes an employee acting on behalf of the Director.

Initiating official means the Supervision Director or another Bureau employee designated by the Director. For purposes of receiving, filing, and serving documents or participating in a supplemental oral response, the initiating official includes an employee acting on behalf of the initiating official.

Nonbank covered person means a covered person, except for persons described in 12 U.S.C. 5515(a) and 5516(a).

Notice of Reasonable Cause and *Notice* mean a Notice issued under § 1091.202.

Person has the definition in 12 U.S.C. 5481.

Respondent means a person who has been issued a Notice of Reasonable Cause under § 1091.202 or who has entered into a consent agreement under § 1091.201.

State has the definition in 12 U.S.C. 5481.

Subpart B—Determination and Voluntary Consent Procedures

§ 1091.201 Voluntary consent to supervisory authority.

(a) At any time, a person and the initiating official may enter into a consent agreement by which the person voluntarily consents to the Bureau's supervisory authority under 12 U.S.C. 5514. The consent agreement shall constitute an order authorized by 12 U.S.C. 5514(a)(1)(C).

(b) A consent agreement under this section does not constitute an admission that a person is a nonbank covered person that is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.

(c) A consent agreement may specify a period of time that the person will be subject to the Bureau's authority under 12 U.S.C. 5514. If the consent agreement specifies a period of time, it shall not be eligible for a petition for termination pursuant to § 1091.301. If the consent agreement does not specify a period of time, the consent agreement will continue until terminated pursuant to § 1091.301.

(d) A consent agreement under this section shall state that the person waives any right to judicial review of the consent agreement.

(e) The initiating official encloses a proposed consent agreement with the Notice of Reasonable Cause in accordance with § 1091.202(c)(6).

§ 1091.202 Notice of Reasonable Cause.

(a) *Generally.* The initiating official is authorized to issue a Notice of Reasonable Cause to a person stating that the Bureau may have reasonable cause to determine that the respondent is a nonbank covered person that is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services.

(b) *Basis of Notice.* A Notice of Reasonable Cause shall be based on:

(1) Complaints collected through the system under 12 U.S.C. 5493(b)(3); and/or

(2) Information from other sources.

(c) *Contents of Notice.* A Notice of Reasonable Cause is subject to the word limit in § 1091.403 and shall contain the following:

(1) A description of the basis for the assertion that the Bureau may have reasonable cause to determine that a respondent is a nonbank covered person that is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services, including a summary of the documents, records, or other items relied on by the initiating official to issue a Notice. Such summary will be consistent with the protection of sensitive information, including compliance with Federal privacy law and whistleblower protections;

(2) A statement that this proceeding is governed by 12 U.S.C. 5514(a)(1)(C) and 12 CFR part 1091;

(3) A statement that failure to respond within 30 days, in the manner specified by § 1091.203, will constitute a waiver of the right to respond and may result in a default determination by the Director;

(4) Instructions for filing documents with the Director;

(5) Instructions for serving documents on the initiating official; and

(6) In an appendix, a proposed consent agreement under § 1091.201.

(d) *Service of Notice.* A Notice of Reasonable Cause shall be served on a respondent by any means that are reasonably calculated to give notice. This includes, but is not limited to, the methods available under 12 CFR 1081.113(d)(1). The initiating official shall promptly file a copy of the Notice and a record of service with the Director.

(e) *Withdrawal of Notice.* The initiating official may withdraw the Notice at any time. Such a withdrawal shall not prevent the initiation of another proceeding under this part.

§ 1091.203 Response.

(a) *Timing and word limit.* Within 30 days of service of a Notice, a respondent shall file any response with the Director and serve it on the initiating official, according to the instructions set forth in the Notice. The response is subject to the word limit in § 1091.403.

(b) *Content of the response.* (1) If the respondent disputes that it is a nonbank covered person that is engaging, or has engaged, in conduct that poses risks to consumers with regard to the offering or provision of consumer financial products or services, the response shall set forth the basis for the respondent's position.

(2) The response shall be accompanied by appendices that include (and are limited to) all documents, records, or other evidence a respondent wishes to use to support the arguments or assertions set forth in the response.

(3) If the respondent wishes to present a supplemental oral response, the

response must include that request. The respondent may also include, for the Director's consideration, the respondent's preference for the supplemental oral response to be by telephone, by video conference, or in person at the Bureau's headquarters in Washington, DC. A respondent's failure to request to present a supplemental oral response shall constitute a waiver of the opportunity to present a supplemental oral response.

(4) The response shall include an email address for serving documents on the respondent, which may be its attorney's email address.

(5) The response shall be accompanied, as an appendix, by an affidavit or declaration, made by the individual respondent if a natural person, or, if a corporate or other entity that is not a natural person, by an officer, managing or general member, or partner authorized to represent the respondent, affirming that the response is true and accurate and does not contain any omissions that would cause the response to be materially misleading.

(c) *Default.* If a respondent does not file a response within the time period set forth in paragraph (a) of this section, it shall constitute a waiver of the respondent's right to respond. At the initiating official's request, the Director may issue a decision and order as provided in § 1091.206(a)(1)).

(d) *No Discovery.* There shall be no discovery in connection with a response.

§ 1091.204 Reply by initiating official.

If the respondent files and serves a response, within 21 days the initiating official may file a reply with the Director and serve it on the respondent. The reply is subject to the word limit in § 1091.403.

§ 1091.205 Supplemental oral response.

(a) If the respondent makes a timely request in a response under § 1091.203 for the opportunity to present a supplemental oral response, the Director shall issue an order setting forth the date, time, and general information relating to the conduct of a supplemental oral response.

(b) There shall be no discovery permitted or witnesses called in connection with a supplemental oral response.

(c) If a respondent is a corporate or other entity, and not a natural person, the respondent shall be represented in any supplemental oral response by:

(1) An officer, managing or general member, or partner authorized to represent the respondent; or

(2) An attorney in good standing of the bar of the highest court of any State.

(d) If a respondent is a natural person, the respondent shall be represented in any supplemental oral response by:

(1) The respondent personally; or

(2) An attorney in good standing of the bar of the highest court of any State.

(e) The Director shall cause an audio recording of a supplemental oral response to be made by a court reporter or other designated person. A respondent may purchase a copy or transcript of the recording at the respondent's own expense.

(f) The initiating official may participate in any supplemental oral response conducted under this section.

(g) A respondent's failure to participate in a supplemental oral response scheduled by the Director shall constitute the respondent's waiver of the opportunity to present a supplemental oral response.

§ 1091.206 Determination by the Director.

(a) Within 60 days after the supplemental oral response, or, if there is no supplemental oral response, the deadline for the reply, the Director shall issue either:

(1) A decision and order subjecting the respondent to the Bureau's supervisory authority pursuant to 12 U.S.C. 5514(a)(1)(C); or

(2) A notification that the Director is terminating the proceeding. Such notification shall have no precedential effect and shall not prevent the initiation of another proceeding under this part.

(b) The Director may, on the Director's own motion at any time before making a determination under paragraph (a) of this section, request that the respondent, initiating official, or both provide any supplemental briefing that Director considers appropriate.

(c) Any decision and order issued by the Director pursuant to paragraph (a)(1) of this section shall include the basis for the decision and an effective date for the order.

(d) Only decisional employees may advise and assist the Director in the consideration and disposition of a proceeding under this part.

(e) A decision and order issued pursuant to paragraph (a)(1) of this section shall constitute final agency action under 5 U.S.C. 704.

Subpart C—Post-Determination Procedures

§ 1091.301 Petition for termination of order.

(a) Any person subject to an order under 1091.206(a)(1) may, no sooner than two years after issuance of such an order and no more frequently than annually thereafter, petition for termination of the order. The same applies to an order under § 1091.201, subject to the limitations in § 1091.201(c).

(b) A petition for termination submitted pursuant to paragraph (a) of this section shall set forth the reasons supporting termination of the order, including any actions taken by a respondent since issuance of the order to address the conduct that led to issuance of the order, and may include any supporting information or evidence that the petitioner believes is relevant to the Director's determination of the matter. A petition for termination must be filed with the Director and served on the initiating official and is subject to the word limit in § 1091.403.

(c) The initiating official shall, within 30 days of receipt of a petition for termination, file a recommendation with the Director and serve it on the respondent. The initiating official's recommendation shall state whether the initiating official recommends that the order be terminated, or modified, or that the petition for termination be denied and the basis for such recommendation. The recommendation is subject to the word limit in § 1091.403.

(d) Not later than 90 days after submission of a petition under paragraph (a) of this section, the Director shall issue a written decision either terminating or modifying the order, or denying the petition. If the Director modifies the order or denies the petition, the Director shall explain the basis for his or her decision with respect to the petition. At any time before issuing a decision, the Director may, on the Director's own motion, request that the respondent and initiating official provide any supplemental briefing that Director considers appropriate.

(e) The decision of the Director made pursuant to paragraph (d) of this section shall constitute final agency action under 5 U.S.C. 704.

Subpart D—Miscellaneous Provisions

§ 1091.401 Methods of filing and serving documents.

(a) *By the respondent.* The respondent files documents with the Director, and serves documents on the initiating official, in accordance with the instructions in the Notice.

(b) *By the initiating official.* The initiating official serves documents on the respondent at the email address specified in the Response (except for service of the Notice, which is governed by § 1091.202(d)). The initiating official

files documents with the Director by any appropriate method.

(c) *By the Director.* The Director serves documents on the respondent at the email address specified in the Response. The Director serves documents on the initiating official by any appropriate method.

(d) *Changes.* Changes to the methods of filing and serving documents are addressed in § 1091.404.

§ 1091.402 Time limits.

In computing any period of time prescribed by this part, or by order of the Director, the date of the act or event that commences the designated period of time is not included. The last day so computed is included unless it is a Saturday, Sunday, or Federal holiday as set forth in 5 U.S.C. 6103(a). When the last day is a Saturday, Sunday, or Federal holiday, the period runs until the end of the next day that is not a Saturday, Sunday, or Federal holiday. Intermediate Saturdays, Sundays, and Federal holidays are included in the computation of time, except when the time period within which an act is to be performed is ten days or less. Changes to time limits are addressed in § 1091.404.

§ 1091.403 Word limits.

(a) *Calculation of word limits.* A Notice, response, reply, petition for termination, or recommendation on a petition for termination must contains no more than 13,000 words. This word limit does not apply to any cover page, table of contents, table of citations, signature block, or appendices. Changes to word limits are addressed in § 1091.404.

(b) *Certification of word count.* A document referenced in paragraph (a) of this section must be accompanied by an appendix stating the number of words in the document, not including any cover page, table of contents, table of citations, signature block, or appendices. It must be signed by counsel for the party filing the document, or by another representative if that party does not have counsel.

§ 1091.404 Changes to methods of filing and service, time limits, and word limits.

(a) *Generally.* This section governs a change to a method of filing or service, to a time limit, or to a word limit, whether prescribed by this part or by the Director. Changes to time limits or word limits are disfavored.

(b) *Change upon consent.* The initiating official and respondent may agree in writing to a change, unless the Director specifies otherwise. The initiating official shall file notice of the change with the Director.

(c) *Change upon written request to Director.* The initiating official or the respondent may file a written request to the Director for a change, for good cause shown. The mere filing of a written request for a change does not alleviate the obligation to meet an applicable requirement, absent written confirmation that the request has been granted.

(c) *Change upon Director's own motion.* The Director may make a change on the Director's own motion.

(e) *No conferral of rights.* Deadlines for action by the Bureau established in this part do not confer any rights on respondents.

§ 1091.405 Confidentiality of proceedings.

(a) *General rule.* In connection with a proceeding under this part, including a petition for termination under § 1091.301, all documents, records or other items submitted by a respondent to the Bureau, all documents prepared by, or on behalf of, or for the use of the Bureau, and any communications between the Bureau and a person, shall be deemed confidential supervisory information under 12 CFR 1070.2(i)(1). However, this paragraph does not apply to the version of a document that is released on the Bureau's website under paragraph (b) of this section.

(b) *Publication of final decisions and orders by the Director.* The Director will make a determination regarding whether a decision or order under § 1091.206(a)(1) or § 1091.301(d) will be publicly released on the Bureau's website, in whole or in part. The respondent may file a submission regarding that issue, within ten days after service of the decision or order. The Director will not release information in a decision or order to the extent it would be exempt from disclosure under 5 U.S.C. 552(b)(4) or (b)(6) or the Director determines there is other good cause. The Director may also decide that any determination regarding public release will itself be released on the website, in whole or in part. Section 1091.206(d) is not applicable to determinations under this paragraph.

§ 1091.406 Multiple respondents.

(a) *Notice issued to multiple respondents.* The initiating official may issue and serve a Notice with respect to multiple respondents. The respondents may elect to make either joint or separate responses to such a Notice under § 1091.203 and be jointly or separately represented at a supplemental oral response under § 1091.205.

(b) *Supplemental Notice to add respondents.* The initiating official may issue a supplemental Notice in a pending proceeding to add one or more respondents. The Director will adopt such procedural steps as may be appropriate to ensure that the added respondents have a reasonable opportunity to respond to the supplemental Notice.

§ 1091.407 Adjudication proceedings otherwise brought by the Bureau.

(a) The Bureau may, in its discretion, provide the notice and opportunity to respond required by 12 U.S.C. 5514(a)(1)(C) in a notice of charges otherwise brought by the Bureau pursuant to 12 CFR 1081.200 and the adjudication proceedings pursuant to part 1081. Also, a person may agree to submit to the Bureau's supervisory authority under 12 U.S.C. 5514(a)(1)(C) as part of a consent order entered into in connection with an adjudication proceeding or civil action.

(b) If the Bureau chooses to proceed in the manner described in paragraph (a) of this section, it shall so indicate in the notice of charges, and any order of the Director resulting from the notice of charges shall constitute the order referred to in 12 U.S.C. 5514(a)(1)(C).

(c) If the Bureau proceeds pursuant to paragraph (a) of this section, the provisions of §§ 1091.201 to 1091.206 and 1091.401 to 1091.406 will be inapplicable to such proceeding.

§ 1091.408 Issue exhaustion.

(a) *Scope.* This section applies to any argument to support a respondent's position, including any argument that could be a basis for setting aside Bureau action under 5 U.S.C. 706 or any other source of law.

(b) *Duties to raise arguments.* A respondent must raise an argument in its written response, or else it is not preserved for judicial review of a proceeding under subpart B. A respondent must raise an argument in its petition for termination, or else it is not preserved for judicial review of a proceeding under subpart C. If the Director requests supplemental briefing, and if a given argument is within the scope of the supplemental briefing requested, the respondent must raise the argument in the supplemental briefing or else it is not preserved for judicial review of a proceeding under subpart B or subpart C, as applicable.

(c) *Manner of raising arguments.* An argument must be raised in a manner that complies with this part and that provides a fair opportunity to consider the argument.

(d) *Discretion to consider unpreserved arguments.* The Director has discretion to consider an unpreserved argument,

including by considering it in the alternative. If the Director considers an unpreserved argument in the alternative, the argument remains unpreserved.

§ 1091.409 No limitation on relief sought in civil action or administrative adjudication.

Nothing in this part shall be construed to limit the relief the Bureau may seek in any civil action or administrative adjudication, including but not limited to, seeking an order to have a person deemed subject to the Bureau's supervisory authority under 12 U.S.C. 5514, including for the reasons set forth in 12 U.S.C. 5514(a)(1)(C).

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2024–08430 Filed 4–22–24; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF STATE

22 CFR Part 62

[Public Notice: 12342]

RIN 1400–AC36

Exchange Visitor Program—General Provisions

AGENCY: U.S. Department of State.

ACTION: Final rule.

SUMMARY: On March 28, 2023, the U.S. Department of State (Department of State) published in the **Federal Register** an interim final rule with request for comment (2023 Interim Final Rule) for the Exchange Visitor Program regulations that apply to sponsors the Department of State designates to conduct international educational and cultural exchange programs. In this final rule, the Department of State responds to public comments submitted in response to the 2023 Interim Final Rule and makes minor revisions to the regulations.

DATES: This rule is effective on May 23, 2024.

FOR FURTHER INFORMATION CONTACT: Rebecca Pasini, Deputy Assistant Secretary of the Office of Private Sector Exchange at SA–5, 2200 C Street NW, Washington, DC 20522 or via email at *JExchanges@state.gov* or phone at (202) 632–9327.

SUPPLEMENTARY INFORMATION: The 2023 Interim Final Rule, effective April 27, 2023 (88 FR 18249), allows sponsors to sign Forms DS–2019 using digital signatures and to transmit Forms DS–2019 electronically to a specified list of recipients. In this final rule, the Department of State addresses the comments that parties submitted in response to the 2023 Interim Final Rule and makes minor revisions to the regulatory language. Most of the 64 commenting parties addressed two topics: sponsor preference for electronic signatures rather than digital signatures, and the need for sponsors to electronically transmit Forms DS–2019 directly to third parties acting on their behalf. After consideration, the Department of State has retained the requirement for digital signatures for signing Forms DS–2019, and it makes no changes to the list of entities to which sponsors may transmit Forms DS–2019 electronically. However, this rule will modify the regulations at 22 CFR 62.12(c)(3) to allow third parties to retrieve Forms DS–2019 directly from sponsors' password-protected computer network systems and/or databases. This modification allows third parties to retrieve copies of digital Forms DS–2019 directly from sponsors that wish to give them such access.

The Department of State also continues to permit sponsors to wet sign and physically mail Forms DS–2019 to exchange visitors and/or third parties. Sponsors that find the functionality of digital signatures too burdensome or costly or wish to continue to send Forms DS–2019 in bulk to third parties are not required to adopt the new procedures.

In addition to commenting on the proposed regulations, many parties submitted questions and/or requests for clarification. To the extent such inquiries relate to this rulemaking, the Department of State will address them herein. Otherwise, the Department of State recommends that interested parties refer to *J1visa.state.gov* for more detailed guidance and/or direct specific queries to the *jexchanges@state.gov* or to one of the category-specific email accounts.

Digital Versus Electronic Signatures

22 CFR 62.12(b)(2)(iii)

Seventeen of the parties submitting comments on the 2023 Interim Final Rule addressed the Department of State's decision to allow Responsible Officers and Alternate Responsible Officers (collectively, Officers) to sign Forms DS–2019 with ''digital'' signature software as opposed to the broader category of ''electronic'' signature software, of which digital is a subset. These parties offered the following reasons in support of their requests that the Department of State allow electronic signatures: (1) the definition of ''digital software'' in the 2023 Interim Final Rule is too vague for sponsors to know whether their software selections meet regulatory requirements; (2) the cryptographical requirements of digital software increase costs and burdens; (3) the vetting of Officers and their limited access to the Student and Exchange Visitor Information System (SEVIS) already provide a high level of security; (4) wet-signed, printed, scanned, and converted-to-portable document format (pdf) Forms DS–2019 are no more or less secure than those signed with electronic signature software and electronically transmitted; (5) it is cumbersome and costly for sponsors with J and F programs to have two operating procedures; (6) the Department of State already accepts electronic signatures on the U.S. Department of Homeland Security's (DHS's) Forms I–20 (Certificate of Eligibility for Nonimmigrant Student Status); and (7) the variety of printed Forms DS–2019 (given different signature, printing, and paper options) may confuse U.S. Government authorities who grant J visas, determine admissibility and entry into the United States, or otherwise review Forms DS–2019. The Department of State considered many of these factors when it originally decided to require the higher level of security that digital signatures offer, and it continues to believe that the benefits of such security overcome the concerns of commenting parties. It addresses each issue individually as follows:

Definition of digital signature. Seven commenting parties expressed confusion over the Department of State's definition of ''digital signature.'' Sponsors can utilize any digital signature software that is an application of technology for cryptographically derived signatures that is supported by a process such as a public key infrastructure and that ensures meaningful authentication of the identity of the signer and integrity of the document. Two examples are DocuSign® and Adobe Acrobat® Sign, and there are numerous other examples of digital signature technologies with which the public may be familiar. In response to questions from commenting parties, the Department of State identifies some examples of signatures that are *not* considered digital for purposes of regulatory compliance: copied and pasted signatures, signatures drawn via computer mouse, and typed signatures. The Department of State continues to believe that sponsors may consult either internal or external information technology experts who can

readily confirm whether a particular software package offers the degree of security necessary to differentiate digital signatures from other types of electronic signatures, thereby meeting the new regulatory requirements.

Increased costs and burdens. Nine commenting parties opined that the implementation of digital signature software would be costly and burdensome. The cost and complexity of implementing digital signature capability varies within the sponsor community, based on many factors. Some sponsors may find that it is not cost effective to implement digital signature capability, and they may opt instead to continue with business as usual (using wet signatures). Other sponsors may have already implemented such capacity, allowing them to benefit from reduced costs and burdens. By retaining the current methodologies while introducing new options, the Department of State allows those sponsors that do not wish to incur different costs or new burdens to maintain their current operating procedures.

SEVIS access vetting provides sufficient security. One commenting party stated that digital signatures were unnecessary since sufficient security was provided by vetting Officers and requiring passwords to access SEVIS. However, the process of signing and transmitting Forms DS–2019 occurs outside of SEVIS, making credentialed access to SEVIS an insufficient protection for these two functions.

Comparability of Electronic Signatures and Wet-Signed and Scanned Signatures. Four commenting parties opined that wet-signed, printed, scanned, and converted-to-pdf Forms DS–2019 offer similar security as electronically signed and transmitted Forms DS–2019s. The Department of State respectfully disagrees. If a fraud investigation involved a Form DS–2019, the form would likely be returned to the sponsor to determine whether a signature was legitimate. At the very least, wet-signed documents—whether transmitted electronically or via mail—bear signatures that are exclusive to a limited group of authorized and vetted signatories. Although wet-signed signatures may be copied, Officers can attest to the authenticity of their signatures and/or whether they recall processing and signing forms that others may suspect are fraudulent.

Visual review of forms signed with most electronic software, however, would not offer any clues as to their legitimacy since most electronic signatures lack both the personalization of wet signatures and the encrypted traceability of digital signatures. For example, electronic signatures may be typed names, typed names in italics, or a signature made with a computer mouse, representations that are difficult to verify as to their source. Further, the volume of forms some Officers process would reduce the likelihood that they could recognize a form as one that they, a coworker, or former employee signed electronically.

Different treatment of Forms DS–2019 and Forms I–20 increases burden and cost. Nine commenting parties expressed concern that having to process Forms DS–2019 differently than Forms I–20 would increase their burden and cost. Sponsors that processed both Forms DS–2019 and Forms I–20 prior to publication of the 2023 Interim Final Rule already followed two separate processes. Since sponsors may continue to print and wet-sign Forms DS–2019, implementation of digital signature software does not disrupt the status quo. That is, sponsors can continue to conduct two processes, and they are not required to adopt a potentially more costly alternative. Moreover, those sponsors that wish to continue wet-signing Forms DS–2019 may now avail themselves of the cost- and time-saving electronic transmission of such forms.

Department of State already accepts electronically signed Forms I–20. Eight commenting parties stated that there was no reason for the Department of State to use a different signing process than DHS requires for Forms I–20. The Department of State and DHS have always independently assessed the risks associated with their respective international exchange programs, and whether electronic signatures offer sufficient security for the Student and Exchange Visitor Program (SEVP) has no bearing on the security requirements for Forms DS–2019. The Department of State has promulgated specific regulations for the Exchange Visitor Program based on its assessment of the risks associated with the Program that may not apply to all SEVP activities.

In their comments, many sponsors sought the capability to transmit Forms DS–2019 electronically to third parties acting on their behalf, citing the important role third parties play in their exchange programs. Although the Department of State continues to prohibit this activity, it has modified the regulations at 22 CFR 62.12(c)(3) to allow sponsors to permit third parties to retrieve copies of digital Forms DS–2019 directly from sponsors' password-protected computer networks and databases, at the sponsors' discretion. It is the Department of State's understanding that the SEVP model does not similarly engage foreign third parties, thereby significantly reducing the need to ensure protection and authenticity of their forms.

Another difference between SEVP activities (for F or M visa classifications) and the Exchange Visitor Program involves the locations at which students and exchange visitors are placed. For example, except for F–1 students placed off-campus, *e.g.,* to obtain practical work experience, participants entering the United States on F-visas are placed exclusively at SEVP-certified academic institutions. However, sponsors in the Private Sector categories of the Exchange Visitor Program (with approximately 200,000 exchange visitors starting new programs each year) for the most part do not similarly place their exchange visitors at their own locations. Non-academic sponsors place exchange visitors at tens of thousands of different private businesses or other organizations that the Department of State does not vet. The sheer number, variety, and location of such placements present greater opportunities for fraud than do placements at a finite number of certified academic institutions. These different levels of risk justify different levels of security.

Different signatures and looks of Forms DS–2019 may confuse authorities. Four commenting parties expressed concern that the variety of physical forms and signature types could confuse U.S. Customs and Border agents, Social Security Administration officials, or even consular officers at U.S. embassies or consulates. Prior to publishing the 2023 Interim Final Rule, the Department of State alerted those entities that routinely process or review Forms DS–2019 of the upcoming regulatory changes. Moreover, in recent consultation with the Department of State's Bureau of Consular Affairs, the Office of Private Sector Exchange confirmed that confusion has been minimal. Going forward, the Department of State is prepared to address any instances of confusion (*e.g.,* turnarounds at ports of entry) should they materialize.

The Department of State has promulgated specific regulations for the Exchange Visitor Program based on its assessment of the risks associated with the Program that may not apply to SEVP activities. For example, after the implementation of SEVIS in 2002, the Department of State required Officers to wet-sign Forms DS–2019 in blue ink to differentiate original documents from forgers. The Department of State, therefore, confirms its decision to permit the more secure digital software,

but not generic electronic signature software.

Transmission of Forms DS–2019

The second most frequently raised concern with the 2023 Interim Final Rule is the limitation on the third parties to which sponsors may electronically transmit Forms DS–2019. Ten parties objected to the exclusion of third parties (as defined in 22 CFR 62.2) of sponsors from the enumerated list of authorized recipients of electronically transmitted forms. Parties generally indicated that the visa interview process is facilitated by providing Forms DS–2019 directly to foreign third parties who perform the critical functions of checking forms for accuracy, helping schedule group interviews, and forwarding batches of Forms DS–2019 to consular sections at posts.

First, the Department of State clarifies that only individuals who are employees of a sponsor are considered ''staff'' for purposes of 22 CFR 62.12(c)(1). Staff at institutions that are designated sponsors are not third parties, and third parties are not considered sponsor staff. Two parties also questioned whether they could copy third parties when they transmit Forms DS–2019 electronically to members of the Department of State's list of acceptable recipients. Since parties receive electronic transmissions regardless of whether they are listed in the ''to'' line or the ''cc'' line of an email message, sponsors may not copy any entities that are not enumerated in 22 CFR 62.12(c)(1).

Five commenting parties asked whether sponsors could provide third parties with password-protected access to their computer network systems and/or databases to allow them to log on to access electronic Forms DS–2019. The Department of State believes that such credentialed access provides a degree of security not available through emailing electronic Forms DS–2019. There are millions of email accounts world-wide as opposed to the small number of third parties to which sponsors would opt to grant network access. The risk of someone gaining inappropriate access to Forms DS–2019 is significantly minimized by restricting access in this way. Accordingly, the Department of State has modified the regulations at 22 CFR 62.12(c)(3) to permit this functionality. As a point of clarification, it notes that for purposes of these regulations, electronic transmission is limited to sponsor-initiated sending of files to individuals or entities, including exchange visitors. Prior to making Forms DS–2019 available for third parties to retrieve, sponsors must either wet sign and convert forms to electronic files or sign the forms with digital signatures since 22 CFR 62.12(b)(2)(i) continues to allow only Officers present in the United States or a U.S. territory to sign Forms DS–2019. The Department of State further reminds sponsors that even in a digital environment, there is only one ''original'' Form DS–2019. If sponsors allow third parties to retrieve Forms DS–2019 from sponsor network systems and/or databases, they must not also mail or electronically transmit the same forms to individuals or entities listed in § 62.12(c)(1). The Department of State has added regulatory language at 22 CFR 62.12(c)(4) to prohibit sponsors from issuing multiple copies of original Forms DS–2019.

For those sponsors that lack the capacity to give third parties password-protected access to their computer network systems and/or databases or do not wish to provide such access, the Department of State reminds them that they may continue to wet-sign Forms DS–2019 and send paper forms to third parties pursuant to 22 CFR 62.12(c)(2).

Other parties expressed concern that Exchange Visitor Program applicants may not have access to email and/or printing facilities. For applicants without email access, sponsors may continue to mail paper forms to applicants and/or to third parties. For applicants without printers at home, the Department of State notes that schools, libraries, and businesses often have printing capabilities that third parties may access for a minimal fee. Nothing in the regulations prohibits exchange visitors from, *e.g.,* emailing Forms DS–2019 to other places, such as offices or friends' homes, for printing. The Department of State believes that these alternatives are sufficient so as not to disrupt the role that third parties play in assisting sponsors and exchange visitors with the visa interview process.

Miscellaneous Comments

Five parties asked for clarification on how the 2023 Interim Final Rule changes the process of providing travel signatures on Forms DS–2019. The new regulations provide flexibility for signing and transmitting Forms DS–2019 to approve travel. First, sponsors may either reprint Forms DS–2019, sign the travel signature space with any color of ink, and send them to exchange visitors using a delivery service; or convert Forms DS–2019 to electronic files and transmit them electronically. Alternatively, Officers may sign the travel signature space of Forms DS–2019 using a digital signature and either transmit them electronically or print them and send them via delivery service. Sponsors that approve travel should advise exchange visitors to carry both Forms DS–2019 when they leave the United States, *i.e.,* the original paper forms and the subsequently issued forms with the travel authorization signature. Parties also questioned whether they should sign reprinted Forms DS–2019 or have exchange visitors send their original Forms DS–2019 or electronic versions of the forms back to their sponsors for processing. The Department of State clarifies that all these options are available to sponsors.

Several parties asked how the new regulations impact use of the ''reprint'' function in SEVIS, noting that sponsors cannot prohibit exchange visitors from reprinting the Forms DS–2019 their sponsors provide. Although the Department of State agrees that sponsors cannot effectively monitor whether exchange visitors reprint or copy Forms DS–2019, the Department of State urges sponsors to advise exchange visitors whose Forms DS–2019 are lost, stolen, or damaged to contact their sponsors and ask for new forms. Sponsors must not electronically transmit or print previously issued Forms DS–2019, but rather, they must use the reprint function in SEVIS and send the new forms (electronically or via mail) to the exchange visitor and/or their accompanying spouse or dependents, if any. On a related matter, two sponsors sought clarification on what sponsors should do if former exchange visitors request copies of their Forms DS–2019 after their programs are over. Since the reprint function is available only for SEVIS records in ''initial'' and ''active'' status, sponsors should inform current exchange visitors of this limitation and encourage them to safeguard their original paperwork.

In the supplemental section of the 2023 Interim Final Rule, the Department of State indicated that it would eliminate the phrase ''or a change in actual and current U.S. address'' from 22 CFR 62.12(a)(3)(vii) because this example was not a valid reason to issue Forms DS–2019. In response to one party's comment that the Department of State did not make this change in the regulatory text, the Department of State now corrects this oversight by deleting the phrase in this final rule.

The 2023 Interim Final Rule eliminated the requirement that Officers who wish to continue to wet-sign paper Forms DS–2019 use only blue ink. In response to one commenting party's request for clarification, the Department of State confirms that it has eliminated the requirement that Officers sign Forms DS–2019 in any specific color of ink.

The introduction of electronic Forms DS–2019 and the potential for the varying physical appearance of printed forms raised questions about exchange visitor signature requirements and signature requirements on other official Department of State forms. Four parties questioned whether the 2023 Interim Final Rule had any impact on signature requirements for, *e.g.,* Forms DS–7002 (Training/Internship Placement Plan). The Department of State clarifies that the Exchange Visitor Program regulations have never required other forms to be signed in a particular color of ink and then distributed via mail delivery service. The requirements set forth in the final rule apply only to Forms DS–2019. One commenting party asked whether exchange visitors were required to sign Forms DS–2019 in ink and another noted that the regulations were silent on whether exchange visitors could transmit Forms DS–2019 electronically. The Department of State notes that this final rule regulates actions of designated sponsors, not exchange visitors.

The addition of electronic Forms DS–2019 has raised other similar issues. Four parties sought clarification with respect to whether the requirement at 22 CFR 62.10(g) that sponsors retain copies of records related to their exchange visitor programs for three years referred to paper or electronic files. Regulations governing the retention of records do not specify the format in which sponsors are required to retain records, leaving it up to sponsors to determine whether they wish to retain paper, electronic, or both paper and electronic records. Electronic records should reflect any changes during the program and be consistent with the information in SEVIS, *e.g.,* exchange visitors' program dates or visa status.

Regulatory Analysis and Notices

Administrative Procedure Act

This final rule responds to public comments received on the 2023 Interim Final Rule and makes minor revisions to the provisions on the control of DS–2019 forms in 22 CFR 62.12. For the reasons set forth in the 2023 Interim Final Rule, the Department of State does not believe 5 U.S.C. 553(b) or (c) apply to this rulemaking.

Congressional Review Act

This regulation is not a major rule as defined by 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with U.S.-based companies in domestic and export markets.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local or Tribal governments, in the aggregate, or by the private sector, of $100 million in any year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*).

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of State has determined that this regulation will not have Tribal implications; will not impose substantial direct compliance costs on Indian Tribal governments; and will not preempt Tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Regulatory Flexibility Act: Small Business Impacts

Since this rule is exempt from section 553 (Rulemaking) and section 554 (Adjudications) of the Administrative Procedure Act, this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.* (1980)).

Executive Orders 12866, 13563, and 14094

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866, as amended by Executive Order 14094, and Executive Order 13563, and affirms that this regulation is consistent with the guidance therein. The Office of Management and Budget (OMB) has designated this rule as not significant under E.O. 12866.

Executive Order 12988

The Department of State has reviewed this rulemaking considering sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens.

Executive Orders 12372 and 13132—Federalism

The Department of State finds that this regulation does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rulemaking relates to OMB Control No. 1405–0119, Certificate of Eligibility for Exchange Visitor Status (J-Nonimmigrant). The Department of State does not anticipate a reportable change in burden for this information collection as a result of this rulemaking.

List of Subjects in 22 CFR Part 62

Cultural exchange programs, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Department of State amends 22 CFR part 62 as follows:

PART 62—EXCHANGE VISITOR PROGRAM

■ 1. The authority citation to part 62 continues to read as follows:

Authority: 8 U.S.C. 1101(a)(15)(J), 1182, 1184, 1258; 22 U.S.C. 1431 *et seq.;* 22 U.S.C. 2451 *et seq.;* 22 U.S.C. 2651a; 22 U.S.C. 6531–6553; Reorganization Plan No. 2 of 1977, 42 FR 62461, 3 CFR 1977 Comp. p. 200; E.O. 12048, 43 FR 13361, 3 CFR, 1978 Comp., p. 168; 8 U.S.C. 1372; section 416 of Pub. L. 107–56, 115 Stat. 354 (8 U.S.C. 1372 note); and 8 U.S.C. 1761–1762.

■ 2. Revise § 62.12 to read as follows:

§ 62.12 Control of Forms DS–2019.

(a) *Issuance of Forms DS–2019.* Sponsors must:

(1) Grant access to SEVIS only to Responsible Officers and Alternate Responsible Officers and ensure that they have access to and use SEVIS to update required information;

(2) Ensure that Responsible Officers and Alternate Responsible Officers input into SEVIS accurate, current, and updated information in accordance with these regulations; and

(3) Issue Forms DS–2019 only for the following purposes if permitted by the regulations and, as necessary, authorized by the Department of State:

(i) To facilitate the initial entry of exchange visitors and accompanying spouses and dependents, if any, into the United States;

(ii) To extend the duration of participation of exchange visitors;

(iii) To facilitate program transfers;

(iv) To replace lost, stolen, or damaged Forms DS–2019;

(v) To facilitate the re-entry into the United States of exchange visitors and accompanying spouses and dependents, if any, who travel outside the United States during exchange visitors' programs;

(vi) To facilitate changes of category;

(vii) To update information when significant changes take place in regard to exchange visitors' programs (*e.g.,*

substantial changes in funding or changes in primary sites of activity);

(viii) To facilitate the correction of minor or technical infractions; and

(ix) To facilitate a reinstatement or reinstatement update SEVIS status.

(b) *Verification.* (1) Prior to issuing Forms DS–2019, sponsors must verify that prospective exchange visitors:

(i) Are eligible for, qualified for, and accepted into the programs in which they will participate;

(ii) Possess adequate financial resources to participate in and complete their exchange visitor programs; and

(iii) Possess adequate financial resources to support accompanying spouses and dependents, if any.

(2) Sponsors must ensure that:

(i) Only Responsible Officers or Alternate Responsible Officers who are physically present in the United States or in a U.S. territory may sign Forms DS–2019 or print original Forms DS–2019;

(ii) Only Responsible Officers or Alternate Responsible Officers whose names are printed on Forms DS–2019 are permitted to sign the forms; and

(iii) Responsible Officers or Alternate Responsible Officers sign paper Forms DS–2019 in ink or sign Forms DS–2019 using digital signature software.

(c) *Transmission of Forms DS–2019.* (1) Sponsors may transmit Forms DS–2019 either electronically (*e.g.,* via email) or by mailing them (*e.g.,* via postal or delivery service) to only the following individuals or entities: exchange visitors; accompanying spouses and dependents, if any; legal guardians of minor exchange visitors; sponsor staff; Fulbright Commissions and their staff; and Federal, State, or local government agencies or departments.

(2) Sponsors may mail signed paper Forms DS–2019 via postal or delivery service to third parties acting on their behalf for distribution to prospective exchange visitors.

(3) Sponsors may provide third parties acting on their behalf with password-protected access to the sponsors' computer network systems and/or databases to retrieve Forms DS–2019.

(4) Sponsors that allow third parties to retrieve Forms DS–2019 from their computer networks and/or databases may not electronically transmit or physically mail the same Forms DS–2019 to individuals or entities identified in paragraph (c)(1) of this section.

(d) *Allotment requests.* (1) *Annual Form DS–2019 allotment.* Sponsors must submit an electronic request via SEVIS to the Department of State for an annual allotment of Forms DS–2019 based on the annual reporting cycle (*e.g.,* academic, calendar, or fiscal year) stated in their letter of designation or redesignation. The Department of State has sole discretion to determine the number of Forms DS–2019 it will issue to sponsors.

(2) *Expansion of program.* Requests for program expansion must include information such as, but not limited to, the justification for and source of program growth, staff increases, confirmation of adequately trained employees, noted programmatic successes, current financial information, additional overseas affiliates, additional third-party entities, explanations of how the sponsor will accommodate the anticipated program growth, and any other information the Department of State may request. The Department of State will take into consideration the current size of a sponsor's programs and the projected expansion of their programs in the next 12 months and may consult with the Responsible Officer and/or Alternate Responsible Officers prior to determining the number of Forms DS–2019 it will issue.

(e) *Safeguards and controls.*

(1) Responsible Officers and Alternate Responsible Officers must always secure their SEVIS User Names and passwords (*i.e.,* not share User Names and passwords with any other person or not permit access to and use of SEVIS by any person).

(2) Sponsors may transmit Forms DS–2019 only to the parties listed in paragraph (c) of this section. However, sponsors must transmit Forms DS–2019 to the Department of State or the Department of Homeland Security upon request.

(3) Sponsors must use the reprint function in SEVIS when exchange visitors' Forms DS–2019 are lost, stolen, or damaged, regardless of whether they are transmitting forms electronically or mailing them.

(4) Sponsors must destroy any damaged and/or unusable Forms DS–2019 (*e.g.,* forms with errors or forms damaged by a printer).

Rebecca Pasini,

Deputy Assistant Secretary, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 2024–08602 Filed 4–22–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5 and 202

[Docket No. FR–6291–F–02]

RIN 2502–AJ60

Revision of Investing Lenders and Investing Mortgagees Requirements and Expansion of Government-Sponsored Enterprises Definition

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Final rule.

SUMMARY: This rule amends the requirements for investing lenders and investing mortgagees to gain or maintain their status as a Federal Housing Administration (FHA) approved lender or mortgagee. This revision makes FHA's approval requirements consistent with investing mortgagees' and investing lenders' risk, reduces barriers to FHA approval for new investing mortgagees and investing lenders, and increases access to capital for all FHA-approved mortgagees and lenders. HUD is clarifying that the general annual certification requirement for lenders and mortgagees is applicable to investing lenders and investing mortgagees. HUD is also defining Government-Sponsored Enterprises (GSEs) separately from other governmental-type entities to ensure that FHA requirements specific to loan origination do not apply to GSEs. Finally, HUD is eliminating obsolete language related to lender and mortgagee net worth requirements. This final rule adopts HUD's July 18, 2023, proposed rule with minor revisions.

DATES: *Effective:* May 23, 2024.

FOR FURTHER INFORMATION CONTACT: Volky Garcia, Division Director, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone 202–402–8229 (this is not a toll-free number), email *Volky.a.garcia@hud.gov.* HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as from individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

Current HUD regulations at 24 CFR part 202, subpart A, establish minimum standards and requirements for the

Secretary to approve lenders and mortgagees to participate in FHA's Title I and Title II programs. Subpart B identifies the classes of lenders and mortgagees eligible to participate in FHA's Title I and Title II programs and outlines additional specific requirements for participation in the programs.

In 2010, HUD amended 24 CFR part 202, subpart A, to include investing lenders and investing mortgagees as a class of lenders and mortgagees subject to HUD's net worth requirements currently found at § 202.5(n). At the time the investing lender and investing mortgagee net worth requirement change was made in 2010, HUD also incorporated new financial reporting, audit, and quality control plan requirements for investing lenders and investing mortgagees into various HUD handbooks; however, no corresponding updates were made to 24 CFR part 202, subpart B, to reflect the investing lender and investing mortgagee requirements. Additionally, FHA increased the minimum net worth requirements applicable to certain classes of lenders and mortgagees in 24 CFR part 202 in 2010. These new net worth requirements were phased in over a period of three years, beginning on May 20, 2010, and becoming fully phased in by May 20, 2013. The net worth requirements during that three-year transition period are now obsolete, but the phased-in net worth requirements language remains in HUD's regulations.

Current HUD regulations at § 202.10 also define the classes of lenders and mortgagees that qualify as governmental institutions, Government-Sponsored Enterprises, public housing agencies, and State housing agencies. Currently, various GSEs [1] are included in the § 202.10(a) definition along with Federal, State, or municipal governmental agencies and Federal Reserve Banks at § 202.10(a). For several years, certain GSEs have contended that they do not have the infrastructure that other lenders and mortgagees listed in § 202.10 have to ensure compliance with FHA requirements related to loan and mortgage origination because they cannot and do not originate loans or mortgages. FHA has reviewed the mission and structure of the GSEs and determined that they should not be subject to FHA requirements specific to loan and mortgage origination because the GSEs do not originate loans or mortgages.

[1] The GSEs are the Federal Home Loan Banks, the Federal Home Loan Mortgage Corporation (commonly known as Freddie Mac), and the Federal National Mortgage Association (commonly known as Fannie Mae).

II. The Proposed Rule

On July 18, 2023, HUD published for public comment a proposed rule (88 FR 45863) to amend 24 CFR parts 5 and 202, which govern numerous administrative requirements for investing lenders and investing mortgagees. The proposed rule sought to add investing lenders and investing mortgagees to the list of entities that must comply with the uniform financial reporting standards found in 24 CFR 5.801(a)(5). The rule proposed to adjust audit and certification requirements for investing lenders and investing mortgagees, as well as to delete obsolete language regarding phased-in net worth requirements currently found at § 202.5(n)(2). In addition, the proposed rule aimed to clarify that investing lenders and investing mortgagees without servicing authority do not have to implement a written quality control plan under § 202.5(h).

III. This Final Rule

The final rule adopts the proposed rule with three changes. First, it makes a clarifying edit to the language of § 202.5(h). In the proposed rule, HUD sought to clarify existing regulatory language and exempt investing lenders and investing mortgagees from the § 202.5(h) requirement that they implement a quality control plan. Public comments stated that the proposed language was unclear. In response, HUD is amending the proposed text of § 202.5(h) to clarify the exception for investing lenders and investing mortgagees.

The second change adds the word ''investing'' before the phrase ''lender or mortgagee'' throughout § 202.9(b)(4) to ensure uniformity in § 202.9(b). This change is not substantive because the section is limited to investing lenders and investing mortgagees by the existing regulatory text and does not change any auditing, compliance, or reporting requirements. In addition, this change will serve to clarify who must submit audit reports under § 202.9(b)(4).

The third change is a non-substantive change that revises the first sentence of § 202.9(a) to clarify the definition of investing lender or investing mortgagee. Specifically, the change adds specific cross-references that more clearly identify when an organization is not an investing lender or investing mortgagee.

IV. Public Comments

The public comment period closed on September 18, 2023, and HUD received four distinct comments related to the proposed rule. The comments were from Housing Finance Authorities (HFAs), a nonprofit that works with HFAs, and an interested individual. A detailed breakdown of the comments and HUD responses is provided below.

Support for the proposed annual certification requirement language in § 202.5(m).

Two commenters supported the proposed amendment to § 202.5(m), which would require investing lenders and investing mortgagees to certify that they have not been refused a license and have not been sanctioned by any State(s) in which it will purchase, hold, sell, or service FHA-approved loans or mortgages.

HUD Response: HUD appreciates the stakeholder feedback in support of the proposed amendment to § 202.5(m).

No concerns with the proposed net worth requirements in § 202.5(n).

One commenter stated that they have no concerns with the proposed capital standards that would require investing lenders and investing mortgagees to maintain a certain net worth based on the size of their portfolios, as detailed by the proposed language for § 202.5(n).

HUD Response: HUD appreciates the stakeholder feedback; however, there is no change to the net worth requirement. Investing lenders and investing mortgagees are already required to comply with the general approval requirements in § 202.5, including the net worth requirements in § 202.5(n). The rule deletes the phased-in net worth requirements for years 2010 and 2011 currently found at § 202.5(n)(2) because the requirements are fully phased-in.

The proposed rule could negatively impact the availability of FHA-approved mortgages.

One commenter stated that the proposed rule would reduce the incentives for investing lenders and investing mortgagees to originate or purchase FHA-insured mortgages because GSEs or other entities that are eligible to purchase or securitize FHA-insured mortgages would face ''lower requirements and fees'' compared to investing lenders and investing mortgagees. The commenter stated that the decrease in demand by investing lenders and investing mortgagees could hurt the viability of FHA's programs and increase the financial risk to FHA's portfolio by centralizing lower quality loans within one institution. The commenter suggested that HUD monitor the impact of the rule on the availability of FHA-supported mortgages or loans after implementation and enact adjustments as needed.

HUD Response: HUD appreciates the commenter's concerns but believes the

impact on availability will be minimal given the provisions of the rule are mostly clarifying in nature with limited changes. This impact is minimal, in part, because investing lenders and investing mortgagees are not authorized to originate Title I loans or Title II mortgages as described in § 202.9(a). In § 202.9, HUD further clarifies the definition of an investing lender and investing mortgagee and updates and clarifies the existing financial statement and audit requirements. With respect to revising the GSE definition, the regulatory text now aligns with the mission and structure of the GSEs. HUD will continue to monitor the availability of FHA-insured mortgages after this rule becomes effective.

Increased risk to FHA's portfolio and the stability of the secondary market.

One commenter stated that the investing requirements and redefinition of the GSEs under the proposed rule, when taken together, could shift many of the loans and mortgages under Title I and Title II to GSEs like Fannie Mae and Freddie Mac. According to the commenter, this centralization could increase the risk to FHA's portfolio as well as reduce the stability and liquidity in the secondary housing market. The commenter recommended that HUD analyze and more thoroughly consider the impact of the proposed rule on the stability and resilience of the secondary mortgage market, as well as on consumer protection.

HUD Response: The rule makes clarifying edits and limited updates to §§ 202.5, 202.9, and 202.10 with respect to the definition of an investing lender and investing mortgagee, investing lender and investing mortgagee financial statement and audit requirements, annual certification language, and the GSE definition. Given that the rule is limited to clarifying edits and minimal updates, HUD does not foresee that the rule will lead to investing lenders or investing mortgagees exiting the secondary market. Accordingly, HUD does not anticipate that the rule will lead to a shift of loans and mortgages to GSEs. In addition, the rule removes obsolete language that is no longer applicable and updates current regulatory citations. HUD will continue to monitor for any secondary market impacts after this rule becomes effective.

The proposed audit requirements are burdensome and unnecessary.

The commenter said the proposed rule would lead to HFAs, that are approved as investing lenders and investing mortgagees, drawing from resources dedicated to substantive projects to ensure compliance with the proposed audit requirement. According to the commenter, this would occur because many programs that HFAs administer do not provide administrative funds while others provide insufficient administrative funds or only enough to barely cover the costs of administering the programs. The commenter also said that these requirements are unnecessary because HFAs, as well as other State and local programs, are subject to substantial public oversight by State auditors, State executives, and State legislatures. The commenter stated that this oversight renders the information sought by HUD duplicative of existing, publicly available information.

HUD Response: The Federal regulations found at § 202.5 exempt HFAs from the auditing requirements, which make it unnecessary for HFAs to draw from resources dedicated to substantive projects to complete these requirements. In addition, HFAs are approved as government mortgagees subject to the requirements of §§ 202.5 and 202.10, and the government mortgagee requirements in the HUD OIG's HUD Consolidated Audit Guide and the FHA Single Family Housing Policy Handbook 4000.1.

HFAs with small portfolios should be exempt from § 202.9(b)(4)(i).

One commenter requested that HUD consider excluding from some or all of the proposed rules HFAs which may technically own FHA mortgages but have a diminishing portfolio that is serviced by an FHA approved mortgagee. The commenter stated the proposed § 202.9(b)(4)(i) requirement that investing lenders and investing mortgagees provide an analysis of escrow funds would be difficult because HFAs do not have access to the required knowledge or information, which is a problem that is amplified when the portfolio is small. The commenter stated that the information is instead possessed by the original or underlying FHA-approved mortgage and should be provided to HUD under current regulations.

HUD Response: The § 202.9(b)(4)(i) requirement pertaining to an analysis of escrow funds is only applicable to investing lenders and investing mortgagees. This section does not apply to HFAs, which are classified as government mortgagees. An HFA, as a government mortgagee, must only comply with the applicable requirements in § 202.5, § 202.10, the HUD Consolidated Audit Guide, and the FHA Single Family Housing Policy Handbook 4000.1. This final rule adds language to the definition of investing lender or investing mortgagee in to § 202.9(a) to more clearly identify organizations that are not investing lenders or investing mortgagees.

The proposed quality control plan language is unclear in § 202.5(h).

Two commenters stated support for exempting investing lenders and investing mortgagees from the requirement that they implement a quality control plan to ensure compliance with the regulation. However, both commenters said the proposed language was ''difficult to parse'' because the clause containing the phrase ''unless approved under § 202.9 without servicing authority'' does not clearly identify that investing lenders and investing mortgagees are exempt from the quality control plan requirement. The commenters suggested the lack of clarity could be addressed by moving the phrase ''without servicing authority'' from its original clause and placing it after the opening phrase of ''lenders or mortgagees.'' One commenter provided a second solution, stating the proposed rule could implement the ''eminently clear'' language from the preamble.

HUD Response: HUD appreciates the commenters' suggested language revisions to § 202.5(h) and has amended the final rule to address the commenters' suggestions. Specifically, HUD has moved the phrase ''unless approved under § 202.9 without servicing authority'' to the end of the sentence. In addition, the sentence has minor clarifying edits.

Lack of clarity on whether entities would be regulated under a single GSE definition and if so, how it would be done.

A commenter said that the proposed rule would expand the definition of GSEs to include any entity that is chartered by Congress to provide secondary market liquidity regardless of whether it is owned or controlled by the Federal Government. Specifically, the commenter stated that the proposed expansion to the definition of GSEs ''could include entities such as Ginnie Mae or Farmer Mac'' that currently have different levels of Federal support than Fannie Mae and Freddie Mac. The commenter also stated that ''the proposed rule does not specify how these entities would be regulated under a single definition of GSEs, or whether there would be a single regulator for all of them.'' The commenter said that this is a problem because the rule does not specify how these entities would be regulated by HUD in a uniform manner or whether there would be a single regulator for all of them. According to the commenter, these issues might create confusion or inconsistency in the

oversight and regulation of these entities.

HUD Response: The final rule aims to distinguish GSEs from all other governmental institutions and does not change which entities fall under the GSE definition. HUD moved the definition of GSE into § 202.10(b) without changing the list of entities meeting the definition. HUD's definition of GSE, which is located at § 202.10(a), includes the Federal Home Loan Banks, Federal Home Loan Mortgage Corporation, and Federal National Mortgage Association. The GSE definition does not include the Governmental National Mortgage Association (Ginnie Mae) or The Federal Agricultural Mortgage Corporation (Farmer Mac). The rule will not change how these entities are regulated but does make clear that GSEs have limited authorizations and are not subject to the FHA requirements that are specific to loan or mortgage origination.

The proposed GSE definition could affect the accountability and transparency of entities like Ginnie Mae and Farmer Mac.

A commenter stated that the proposed definition of GSEs could reduce the accountability and transparency of Ginnie Mae and Farmer Mac, as well as their access to Federal subsidies and support. The commenter said that this could happen because ''Ginnie Mae has an explicit guarantee from the Federal Government that its securities will be paid, while Farmer Mac has no explicit guarantee from the Federal Government but has some tax exemptions and borrowing privileges.'' This concern led the commenter to suggest that HUD ensure that these entities are subject to adequate oversight, supervision, and disclosure by their regulators, Congress, and the public.

HUD Response: Current regulation combines governmental institutions and GSEs in its definition, requiring GSEs to follow policy specific to loan origination even though they do not originate FHA loans. The final rule defines GSEs separate and apart from all other governmental institutions and reduces the administrative burden of having to adhere to compliance requirements that are not related to the functions they are performing. The final rule makes clear that GSEs have limited authorizations and are not subject to the FHA requirements that are specific to loan or mortgage origination. Also, the GSE definition does not include Ginnie Mae and Farmer Mac. This exclusion means that changes to the GSE definition will not lead to transparency issues with Ginnie Mae and Farmer Mac. HUD does not foresee an impact on the secondary housing market but will continue to monitor this after the rule becomes effective.

The proposed GSE definition could impact Fannie Mae's and Freddie Mac's conservatorship reform.

One commenter stated that the proposed rule would affect the role and function of Fannie Mae and Freddie Mac in the housing finance system, which is currently undergoing a major reform process. The commenter said the reform process aims to end the conservatorship of Fannie Mae and Freddie Mac, which has been in place since 2008, and to establish a more competitive and efficient secondary mortgage market. The commenter warned the proposed rule could have implications for the timing and outcome of the reform process, as well as for the future structure and governance of Fannie Mae and Freddie Mac.'' The commenter suggested that HUD coordinate with other Federal agencies to ensure consistency and alignment of policies and standards related to housing finance reform.

HUD Response: Certain GSEs, unlike many other lenders or mortgagees, do not have the infrastructure available to ensure compliance with FHA requirements. The final rule relieves GSEs of these requirements by defining GSEs separate and apart from all other governmental institutions. This definition makes clear that GSEs have limited authorizations and does not amend the programs or services provided by Fannie Mae and Freddie Mac. Given that the final rule only changes compliance requirements to ensure appropriateness with the limited nature of authorizations for GSEs, HUD does not believe the change will impact the role and function of Fannie Mae and Freddie Mac in the housing finance system or the Federal Housing Finance Agency's oversight of Fannie Mae and Freddie Mac.

GSE exclusion based on origination authority should apply to similarly situated HFAs.

One commenter stated that the reasoning provided in the proposed rule for excluding GSEs from FHA requirements specific to loan or mortgage origination, which is that GSEs cannot originate loans, is applicable to many HFAs. The commenter recommended that these similarly situated HFAs be treated like GSEs and be exempted from the loan or mortgage origination requirements as appropriate.

HUD Response: HUD notes that all HFAs that currently participate in FHA's Title I and Title II programs are approved as government mortgagees authorized to perform activities associated with loan or mortgage origination. While FHA understands from the commenters that not all HFAs currently originate, or are authorized to originate, HFA lending activities and authorizations can change over time. HUD also lacks the information needed to make an informed and reasoned judgment on whether it is appropriate to depart from the existing requirements for HFAs, as well as how such a change would be implemented, at this time. Accordingly, FHA is maintaining the current framework in § 202.10(a) for HFAs.

V. Findings and Certifications

Regulatory Review—Executive Orders 12866, 13563, and 14094

Pursuant to Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The order also directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 further directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter referred to as the ''Modernizing E.O.'') amends section 3(f) of Executive Order 12866, among other things.

As discussed above, this rule defines GSEs under a separate definition within § 202.10. It clarifies the audit, financial statement, and certification requirements of investing lenders and investing mortgagees. It eliminates obsolete net worth requirements for investing lenders and investing mortgagees. This rule was determined not to be a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866 as amended by Executive Order 14094.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The changes in this rule are limited to defining GSEs under a separate definition within § 202.10; clarifying the audit, financial statement, and certification requirements of investing lenders and investing mortgagees; and eliminating obsolete language within 24 CFR part 202 regarding lenders and mortgagees net worth requirements. The minor nature of changes led HUD to conclude that the proposed rule was non-significant, a finding later affirmed by OMB. HUD solicited comments from the public at the proposed rule stage and received no comments suggesting that it would impose a significant economic impact on a substantial number of small entities. In addition, HUD is only making a minor clarifying edit to the final rule in response to public comments. Accordingly, the undersigned certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Environmental Impact

This rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 under 24 CFR 50.19(c)(1) because it does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, rehabilitation, alteration, demolition, or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy.

Executive Order 13132, Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either: (i) imposes substantial direct compliance costs on State and local governments and is not required by statute, or (ii) preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This rule does not impose any Federal mandates on any State, local, or Tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Crime, Government contracts, Grant programs—housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 202

Administrative practice and procedure, Home improvement, Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends 24 CFR parts 5 and 202 as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

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

Authority: 12 U.S.C. 1701x; 42 U.S.C. 1437a, 1437c, 1437f, 1437n, 3535(d); 42 U.S.C. 2000bb *et seq.;* 34 U.S.C. 12471 *et seq.;* Sec. 327, Pub. L. 109–115, 119 Stat. 2396; E.O. 13279, 67 FR 77141, 3 CFR, 2002 Comp., p. 258; E.O. 13559, 75 FR 71319, 3 CFR, 2010 Comp., p. 273; E.O. 14015, 86 FR 10007, 3 CFR, 2021 Comp., p. 517.

■ 2. In § 5.801, revise paragraph (a)(5) to read as follows:

§ 5.801 Uniform financial reporting standards.

(a) * * *

(5) HUD-approved Title I and Title II supervised, nonsupervised, and investing lenders and investing mortgagees.

* * * * *

PART 202—APPROVAL OF LENDING INSTITUTIONS AND MORTGAGEES

■ 3. The authority citation for part 202 continues to read as follows:

Authority: 12 U.S.C. 1703, 1709, and 1715b; 42 U.S.C. 3535(d).

■ 4. In § 202.5, revise paragraph (h), (m) introductory text, and (n)(1) and (2), and remove paragraph (n)(3) to read as follows:

§ 202.5 General approval standards.

* * * * *

(h) *Quality control plan.* Lenders or mortgagees shall implement a written quality control plan, acceptable to the Secretary, that assures compliance with the regulations of this chapter and other issuances of the Secretary regarding loan or mortgage origination and servicing unless the lenders or mortgagees were approved under § 202.9 without servicing authority.

* * * * *

(m) *Reports.* Each lender and mortgagee must submit an annual certification on a form prescribed by the Secretary. Upon application for approval and with each annual recertification, each lender and mortgagee must submit a certification that it has not been refused a license and has not been sanctioned by any State or States in which it will originate, purchase, hold, sell, or service insured mortgages or Title I loans. In addition, each mortgagee shall file the following:

* * * * *

(n) * * *

(1) *Applicability.* The requirements of paragraph (n) of this section apply to approved supervised and nonsupervised lenders and mortgagees under §§ 202.6 and 202.7, and approved investing lenders and investing mortgagees under § 202.9. For ease of reference, these institutions are referred to as ''approved lenders or mortgagees'' for purposes of paragraph (n) of this section. These requirements also apply to applicants for FHA approval under §§ 202.6, 202.7, and 202.9. For ease of reference, these institutions are referred to as ''applicants'' for purposes of paragraph (n) of this section.

(2) *Requirements*—(i) *Single family net worth requirements.* Irrespective of size, each applicant and each approved lender or mortgagee for participation solely under the FHA single family programs shall have a net worth of not less than $1 million, plus an additional net worth of one percent of the total volume, in excess of $25 million, of FHA single family insured mortgages originated, underwritten, purchased, or serviced during the prior fiscal year, up to a maximum required net worth of $2.5 million. No less than 20 percent of the applicant's or approved lender's or mortgagee's required net worth must be liquid assets consisting of cash or its equivalent acceptable to the Secretary.

(ii) *Multifamily net worth requirements.* Irrespective of size, each applicant for approval and each approved lender or mortgagee for participation solely under the FHA multifamily programs shall have a net worth of not less than $1 million. For those multifamily approved lenders or mortgagees that also engage in mortgage servicing, an additional net worth of one percent of the total volume, in excess of $25 million, of FHA multifamily mortgages originated, purchased, or serviced during the prior fiscal year, up to a maximum required net worth of $2.5 million. For multifamily approved lenders or mortgagees that do not perform mortgage servicing, an additional net worth of one half of one percent of the total volume, in excess of $25 million, of FHA multifamily mortgages originated during the prior fiscal year, up to a maximum required net worth of $2.5 million. No less than 20 percent of the applicant's or approved lender's or mortgagee's required net worth must be liquid assets consisting of cash or its equivalent acceptable to the Secretary.

(iii) *Dual participation net worth requirements.* Irrespective of size, each applicant for approval and each approved lender or mortgagee that is a participant in both FHA single family and multifamily programs must meet the net worth requirements as set forth in paragraph (n)(2)(i) of this section.

* * * * *

■ 6. In § 202.9:

■ a. Revise the section heading and paragraph (a);

■ b. In paragraphs (b) introductory text and (b)(1) and (2), remove the words ''investing lender or mortgagee'' and add, in their place, the words ''investing lender or investing mortgagee''; and

■ c. Revise paragraph (b)(3) and add paragraph (b)(4).

The revisions and addition read as follows:

§ 202.9 Investing lenders and investing mortgagees.

(a) *Definition.* An investing lender or investing mortgagee is an organization that is not approved as a supervised lender or mortgagee under § 202.6, a nonsupervised lender or mortgagee under § 202.7, or a governmental or similar institution under § 202.10. An investing lender or investing mortgagee may purchase, hold, or sell Title I loans or Title II mortgages, respectively, but may not originate Title I loans or Title II mortgages in its own name or submit applications for the insurance of mortgages. An investing lender or investing mortgagee may not service Title I loans or Title II mortgages without prior approval of the Secretary.

(b) * * *

(3) *Fidelity bond.* An investing lender or investing mortgagee shall maintain fidelity bond coverage and errors and omissions insurance acceptable to the Secretary and in an amount required by the Secretary, or alternative insurance coverage approved by the Secretary, that assures the faithful performance of the responsibilities of the mortgagee.

(4) *Audit report.* An investing lender or mortgagee must comply with the financial reporting requirements in24 CFR part 5, subpart H. Audit reports shall be based on audits performed by a certified public accountant, or by an independent public accountant licensed by a regulatory authority of a State or other political subdivision of the United States on or before December 31, 1970. Audit reports shall include:

(i) A financial statement in a form acceptable to the Secretary, including a balance sheet and a statement of operations and retained earnings, a statement of cash flows, an analysis of the investing lender's or mortgagee's net worth adjusted to reflect only assets acceptable to the Secretary, and an analysis of escrow funds; and

(ii) Such other financial information as the Secretary may require to determine the accuracy and validity of the audit report.

■ 7. In § 202.10:

■ a. Revise paragraph (a);

■ b. Remove paragraph (c);

■ c. Redesignate paragraph (b) as paragraph (c); and

■ d. Add new paragraphs (b) and (d).

The revision and additions read as follows:

§ 202.10 Governmental institutions, Government-Sponsored Enterprises, public housing agencies and State housing agencies.

(a) *Federal, state, and municipal governmental agencies and Federal Reserve Banks.* A Federal, State, or municipal government agency or a Federal Reserve Bank may be an approved lender or mortgagee. A mortgagee approved under this paragraph (a) may submit applications for Title II mortgage insurance. A lender or mortgagee approved under this paragraph (a) may originate, purchase, service, or sell Title I loans and insured mortgages, respectively. A mortgagee or lender approved under this paragraph (a) is not required to meet a net worth requirement. A lender or mortgagee shall maintain fidelity bond coverage and errors and omissions insurance acceptable to the Secretary and in an amount required by the Secretary, or alternative insurance coverage approved by the Secretary, that assures the faithful performance of the responsibilities of the mortgagee. There are no additional requirements beyond the general approval requirements in § 202.5 or as provided under paragraph (c) of this section.

(b) *Government-Sponsored Enterprises.* The Government-Sponsored Enterprises are the Federal Home Loan Banks, Federal Home Loan Mortgage Corporation, and Federal National Mortgage Association. A Government-Sponsored Enterprise may be an approved lender or mortgagee. A lender or mortgagee approved under this paragraph (b) may purchase, service, or sell Title I loans and insured mortgages, respectively. A mortgagee or lender approved under this paragraph (b) is not required to meet a net worth requirement. There are no additional requirements beyond the general approval requirements in § 202.5.

* * * * *

(d) *Audit requirements.* The insuring of loans and mortgages under the Act constitutes ''Federal financial assistance'' (as defined in 2 CFR 200.1) for purposes of audit requirements set out in 2 CFR part 200, subpart F. Non-Federal entities (as defined in 2 CFR 200.1) that receive insurance as lenders and mortgagees shall conduct audits in accordance with 2 CFR part 200, subpart F.

Julia R. Gordon,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2024–08648 Filed 4–22–24; 8:45 am]

BILLING CODE 4210–67–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0077; FRL–11855–01–OCSPP]

Cyclaniliprole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyclaniliprole in or on Vegetable, cucurbit, group 9. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 23, 2024. Objections and requests for hearings must be received on or before June 24, 2024, and must be filed in

accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2023–0077, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2023–0077 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before June 24, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2023–0077, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 9, 2024 (89 FR 9103) (FRL–10579–12–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E9037) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to establish a tolerance for residues of the insecticide cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[(1-cyclopropylethyl)amino carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, including its metabolites and degradates, in or on the raw agricultural commodity Vegetable, cucurbit, group 9 at 0.3 parts per million (ppm). Upon the establishment of the tolerance specified above, IR–4 requested to remove the established tolerance for Vegetable, cucurbit, group 9 at 0.15 ppm. The document referenced a summary of the petition, which is available in the docket at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyclaniliprole, including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with cyclaniliprole follows.

No single or repeated dose study performed by any route of exposure produced an adverse effect following cyclaniliprole exposure at dose levels below, at, or above the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)). Although the oral toxicity studies in dogs were conducted at approximately a third of the limit dose, no adverse effects were seen. While adaptive liver effects were seen in these studies, it is unlikely that cyclaniliprole would produce adverse liver effects if tested at higher doses in dogs as a structurally related chemical, chlorantraniliprole,

was tested up to the limit dose in dogs and did not demonstrate adverse liver effects. There is no evidence that cyclaniliprole produces increased susceptibility with prenatal or postnatal exposures. Cyclaniliprole is considered not likely to be carcinogenic based on no increase in treatment-related tumor incidence in carcinogenicity studies in rats and mice and no genotoxicity.

Specific information on the studies received for cyclaniliprole as well as the no-observed-adverse-effect-level (NOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document, ''Cyclaniliprole: Human Health Risk Assessment for New Greenhouse Uses on Lettuce and Cucumber and Amendment of Permanent Tolerances on Cucurbit Vegetables Crop Group 9'', in docket ID number EPA–HQ–OPP–2023–0077.

Based on the review of the available cyclaniliprole toxicological studies, no toxicity endpoints or points of departure were selected for risk assessment. Based on the toxicological profile of cyclaniliprole, EPA has concluded that the FFDCA requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) requires an additional tenfold margin of safety in the case of threshold risks, which cyclaniliprole does not present. Section 408(b)(2)(D)(v) requires consideration of information concerning cumulative effects of substances that have a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyclaniliprole and any other substances, and cyclaniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyclaniliprole has a common mechanism of toxicity with other substances.

Cyclaniliprole has been grouped with the pyridyl pyrazoles. As part of the ongoing process to review registered pesticides, the Agency intends to apply this framework to determine if the available toxicological data for cyclaniliprole suggests a candidate common mechanism group (CMG) may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

There is a potential for exposure to cyclaniliprole residues via food and drinking water based on existing uses and the proposed uses for cyclaniliprole application directly to growing crops. These applications can also result in cyclaniliprole reaching surface and ground water, both of which can serve as sources of drinking water. There are no proposed uses in residential settings and therefore no anticipated residential exposures, although exposures resulting from spray drift from agricultural applications onto residential areas may occur. However, no quantitative risk assessment was conducted because no toxicity endpoints or points of departure were selected for risk assessment.

Determination of safety. Based on the available data indicating a lack of adverse effects from exposure to cyclaniliprole, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyclaniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry (LC–MS/MS)) is available to enforce the tolerance expression for plant and livestock commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Mead, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are Codex MRLs established for residues of cyclaniliprole on cucumber and squash (summer) at 0.05 ppm; and melons, pumpkin, squash (winter) at 0.1 ppm which are different than the U.S. tolerance for the cucurbit vegetable group 9 established in this action (0.3 ppm). For cucurbit vegetable group 9, no harmonization is possible for these commodities because decreasing the tolerance level to harmonize with the Codex MRL could put U.S. growers at risk of violative residues despite legal use of cyclaniliprole.

V. Conclusion

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops, EPA is revising the tolerance for residues resulting from direct applications to the cucurbit vegetable group 9 because the petitioner requested it for international trade purposes. Therefore, the tolerance for residues of cyclaniliprole in or on Vegetable, cucurbit, group 9 is revised from 0.15 ppm to 0.3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian

Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: April 11, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.694, amend Table 1 to Paragraph (a) by revising the entry for ''Vegetable, cucurbit, group 9'' to read as follows:

§ 180.694 Cyclaniliprole; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * * * *	
Vegetable, cucurbit, group 9	0.3
* * * * * * *	

* * * * *

[FR Doc. 2024–08022 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 89, No. 79
Tuesday, April 23, 2024

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1007; Project Identifier MCAI–2023–01249–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–13–11, which applies to all Airbus SAS Model A350–941 and –1041 airplanes. AD 2022–13–11 requires revising the existing airplane flight manual (AFM) for airplanes equipped with affected flight control units (FCUs) and replacing any affected FCU with a serviceable FCU. Since the FAA issued AD 2022–13–11, the FAA has determined that it is necessary to expand the applicability of the AFM revision requirement to all Model A350–941 and –1041 airplanes, including those equipped with serviceable FCUs. This proposed AD would continue to require certain actions in AD 2022–13–11, including replacing any affected FCU with a serviceable FCU, expand the requirement to revise the existing AFM for all airplanes, and prohibit the installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). 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 June 7, 2024.

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–2024–1007; 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 material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2024–1007.
- 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.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 562–627–5357; email: *dat.v.le@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–2024–1007; Project Identifier MCAI–2023–01249–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 this 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 Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 562–627–5357; email: *dat.v.le@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

The FAA issued AD 2022–13–11, Amendment 39–22097 (87 FR 39741, July 5, 2022) (AD 2022–13–11), for all Airbus SAS Model A350–941 and –1041 airplanes. AD 2022–13–11 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2021–0260, dated November 18, 2021, to correct an unsafe condition.

AD 2022–13–11 requires revising the existing AFM to include a procedure on the use of the AFS control panel ALT knob. AD 2022–13–11 also requires replacing any affected FCU with a serviceable FCU, which would terminate the AFM revision following that replacement. The FAA issued AD

2022–13–11 to address erroneous target altitude during descent, climb, or go-around, which could result in an unexpected vertical trajectory deviation and loss of correct situational awareness that could potentially result in uncontrolled impact with the ground.

Actions Since AD 2022–13–11 Was Issued

Since the FAA issued AD 2022–13–11, EASA superseded 2021–0260 and issued EASA AD 2023–0215, dated December 11, 2023; corrected December 13, 2023 (EASA AD 2023–0215) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes. EASA AD 2023–0215 states that since EASA AD 2021–0260 was issued, several operators reported uncommanded altitude changes on airplanes equipped with serviceable FCUs. Airbus is investigating the cause of these reported events and, as a precautionary measure, expanded the applicability of the AFM Temporary Revision (TR) 121, issue 1.0, to all airplanes, including those equipped with serviceable FCUs. For the reasons described above, EASA AD 2023–0215 partially retains the requirements of the EASA AD 2021–0260, which is superseded, and requires amendment of the applicable AFM by incorporating the AFM TR 121, issue 1.0, for airplanes equipped with serviceable FCUs. EASA AD 2023–0215 is still considered to be an interim action, and further EASA AD action may follow.

The FAA is proposing this AD to address erroneous target altitude during descent, climb, or go-around, which could result in an unexpected vertical trajectory deviation and loss of correct situational awareness that could potentially result in uncontrolled impact with the ground. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1007.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2022–13–11, this proposed AD would retain certain requirements of AD 2022–13–11. Those requirements are referenced in EASA AD 2023–0215, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0215 specifies procedures for revising the existing AFM to include a procedure on the use of the AFS control panel ALT knob for all Airbus SAS Model A350–941 and –1041 airplanes, including the airplanes equipped with serviceable FCUs part number (P/N) C31006AD01; and replacing any affected FCU having P/N C31006AC01 or C31006AB01 with a serviceable FCU having P/N C31006AD01. EASA AD 2023–0215 also prohibits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been 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 referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2022–13–11. This proposed AD would require accomplishing the actions specified in EASA AD 2023–0215 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Compliance With AFM Revisions

EASA AD 2023–0215 requires operators to ''inform all flight crews'' of revisions to the AFM, and thereafter to ''operate the aeroplane accordingly.'' However, this proposed AD would not specifically require those actions as those actions are already required by FAA regulations. FAA regulations require operators furnish to pilots any changes to the AFM (for example, 14 CFR 121.137), and to ensure the pilots are familiar with the AFM (for example, 14 CFR 91.505). As with any other flightcrew training requirement, training on the updated AFM content is tracked by the operators and recorded in each pilot's training record, which is available for the FAA to review. FAA regulations also require pilots to follow the procedures in the existing AFM including all updates. 14 CFR 91.9 requires that any person operating a civil aircraft must comply with the operating limitations specified in the AFM. Therefore, including a requirement in this proposed AD to operate the airplane according to the revised AFM would be redundant and unnecessary.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0215 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0215 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0215 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0215. Service information required by EASA AD 2023–0215 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–1007 after the FAA final rule is published.

Interim Action

The FAA considers that this proposed AD would be an interim action. The FAA anticipates that further AD action will follow.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 27 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
Up to 6 work-hours × $85 per hour = $510	$27,000	Up to $27,510	Up to $742,770.

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:

■ a. Removing Airworthiness Directive (AD) 2022–13–11, Amendment 39–22097 (87 FR 39741, July 5, 2022); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2024–1007; Project Identifier MCAI–2023–01249–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 7, 2024.

(b) Affected ADs

This AD replaces AD 2022–13–11, Amendment 39–22097 (87 FR 39741, July 5, 2022) (AD 2022–13–11).

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 22, Auto Flight.

(e) Unsafe Condition

This AD was prompted by a report of inadvertent auto flight system (AFS) altitude changes on the flight control unit (FCU); an investigation revealed that, depending on the ring selection, failure of the ALT knob on the FCU could change the target altitude. The FAA is issuing this AD to address erroneous target altitude during descent, climb, or go-around, which could result in an unexpected vertical trajectory deviation and loss of correct situational awareness that could potentially result in uncontrolled impact with the ground.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0215, dated December 11, 2023; corrected December 13, 2023 (EASA AD 2023–0215).

(h) Exceptions to EASA AD 2023–0215

(1) Where EASA AD 2023–0215 refers to ''02 December 2021 [the effective date of EASA AD 2021–0260],'' this AD requires using August 9, 2022 (the effective date of AD 2022–13–11).

(2) Where EASA AD 2023–0215 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraphs (1) and (2) of EASA AD 2023–0215 specify to ''inform all flight crews, and thereafter, operate the aeroplane accordingly,'' this AD does not require those actions as those actions are already required by existing FAA operating regulations.

(4) The ''Remarks'' section of EASA AD 2023–0215 does not apply to this AD.

(i) 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 manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(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 EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 562–627–5357; email: *dat.v.le@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) European Union Aviation Safety Agency (EASA) AD 2023–0215, dated December 11, 2023; corrected dated December 13, 2023.

(ii) [Reserved]

(3) For EASA AD 2021–0260 and EASA AD 2023–0215, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu*. You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

Issued on April 17, 2024.

Victor Wicklund,

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

[FR Doc. 2024–08561 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1005; Project Identifier AD–2022–00996–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 767–300 series airplanes. This proposed AD was prompted by a report that some Model 767–300 series airplanes that had been converted into a freighter configuration are missing an electrical bracket for a wire bundle in the main equipment center. This proposed AD would require installing an electrical support bracket and re-installing wire bundles. 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 June 7, 2024.

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–2024–1005; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd, MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1005.

FOR FURTHER INFORMATION CONTACT: Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St, Des Moines, WA 98198; phone: 206–231–3415; email: *samuel.j.dorsey@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–2024–1005; Project Identifier AD–2022–00996–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 this 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 Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St, Des Moines, WA 98198; phone: 206–231–3415; email: *samuel.j.dorsey@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report that certain Model 767–300 series airplanes that have been modified to operate in a freighter configuration by the manufacturer (also referred to as a ''767–300 Boeing Converted Freighter'' or ''767–300BCF'') do not have the correct airplane configuration necessary to comply with the requirements of AD 2020–18–16, Amendment 39–21237 (85 FR 62993, October 6, 2020) (AD 2020–18–16). Specifically, these Model 767–300 series airplanes are missing an electrical support bracket in the main equipment center, leading to inadequate separation of a wire bundle that includes fuel quantity indicating system (FQIS) wiring.

During the design of the replacement cargo floor beams for the freighter conversion, although the bracket and attached wire support clamps were a required design feature to protect the FQIS wiring, the bracket and clamps were omitted from the design of the cargo floor beams. When the passenger configuration floor beams were replaced with the cargo configuration floor beams during modification, the bracket was therefore removed but not replaced. In addition, on some airplanes, clamps were installed around the relevant wire bundles but were not attached to the missing bracket.

In either case, the wire bundles that were previously attached to the bracket were left unsecured, affecting the wire separation configuration requirements for the FQIS wiring as defined in the airworthiness limitations (Critical

Design Configuration Control Limitation 28–AWL–09).

This condition, if not addressed, could result in an electrical fault condition in the FQIS wiring, possibly creating an ignition source in the center wing fuel tank. A failure to prevent possible ignition sources in the fuel tank, in combination with flammable fuel vapors, could result in an explosion and consequent loss of the airplane.

AD 2020–18–16 applies to certain Model 767–200, –300, –300F, and –400ER series airplanes and requires modification of the FQIS to prevent ignition sources inside the center fuel tank. Paragraph (h) of AD 2020–18–16 contains optional alternative requirements for cargo airplanes. The electrical support bracket required by this proposed AD is needed for some Model 767–300 cargo airplanes to accomplish the service bulletin required by the alternative actions in paragraph (h)(2)(ii) of AD 2020–18–16. This proposed AD would restore the airplane to a configuration where paragraph (h)(2)(ii) of AD 2020–18–16 may be accomplished.

FAA's Determination

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.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022. This service information specifies procedures for installing an electrical support bracket in the main equipment center and re-installing wire bundles. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions identified as ''RC'' (required for compliance) in the Accomplishment Instructions of Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022, already described, except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this service information at *regulations.gov* under Docket No. FAA–2024–1005.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 18 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installation of bracket	3 work-hours × $85 per hour = $255	$93	$348	$6,264

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:

The Boeing Company: Docket No. FAA–2024–1005; Project Identifier AD–2022–00996–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 7, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 767–300 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by a report that some Model 767–300 series airplanes that have been modified to operate in a freighter configuration are missing an electrical bracket for a wire bundle in the main equipment center, which affects wire separation configuration requirements for fuel quantity indicating system wiring and could result in an electrical fault condition. The FAA is issuing this AD to prevent possible ignition sources in the fuel tank due to an electrical fault, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022.

(h) Exceptions to Service Information Specifications

Where the ''Compliance'' paragraph of Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022, refers to the Revision 1 date of this service bulletin, this AD requires using the effective date of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 767–24–0261, dated May 19, 2021.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety 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 certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as specified by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(4)(i) and (ii) of this AD apply.

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

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

(k) Related Information

(1) For more information about this AD, contact Samuel Dorsey, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3415; email: *samuel.j.dorsey@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(l) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 767–24A0261, Revision 1, dated August 17, 2022.

(ii) [Reserved]

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

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

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

Issued on April 17, 2024.

Victor Wicklund,

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

[FR Doc. 2024–08550 Filed 4–22–24; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1006; Project Identifier MCAI–2023–01222–T]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by 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 MHI RJ Aviation ULC Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes. This proposed AD was prompted by a notice from a supplier reporting that torque wrenches used to install the air driven generator (ADG) downlock cam nut were out of calibration, which resulted in a higher torque level setting than required during the initial production installation of the affected cam nut. This proposed AD would require replacement of the affected ADG locking cam screw and cam nut, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). 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 June 7, 2024.

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–2024–1006; 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 Transport Canada material that is proposed for IBR in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.* It is also available at *regulations.gov* under Docket No. FAA–2024–1006.

• 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.

FOR FURTHER INFORMATION CONTACT: Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *Fatin.R.Saumik@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–2024–1006; Project Identifier MCAI–2023–01222–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 this 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 Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *Fatin.R.Saumik@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–2023–76, dated November 28, 2023 (Transport Canada AD CF–2023–76) (also referred to as the MCAI), to correct an unsafe condition for certain MHI RJ Aviation ULC Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes. The MCAI states MHI RJ Aviation received a supplier quality escape notice, reporting that torque wrenches used to install the ADG downlock cam nut were out of calibration, which resulted in a higher torque level setting than required during the initial production installation of the affected cam nut. This over-torque condition could cause the screw and cam to fail, which, if not corrected, could result in the loss of the ADG downlock mechanism functionality upon airplane touchdown which eliminates a critical power source for the aircraft, leaving the flight crew with the minimum flightdeck displays and difficulty controlling the aircraft.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1006.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–76 specifies procedures for replacing the affected ADG locking cam screw and cam nut. 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**.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2023–76 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2023–76 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–76 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by Transport Canada AD CF–2023–76 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–1006 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 24 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
Up to 2 work-hours × $85 per hour = $170	$285	Up to $455	Up to $10,920.

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:

MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Docket No. FAA–2024–1006; Project Identifier MCAI–2023–01222–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 7, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (Type Certificate previously held by Bombardier, Inc.) Model CL–600–2D15 (Regional Jet Series 705) and Model CL–600–2D24 (Regional Jet Series 900) airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–76, dated November 28, 2023 (Transport Canada AD CF–2023–76).

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Unsafe Condition

This AD was prompted by a notice from a supplier reporting that torque wrenches used to install the air driven generator (ADG) downlock cam nut were out of calibration, which resulted in a higher torque level setting than required during the initial production installation of the affected cam nut. The FAA is issuing this AD to address this over-torque condition that could cause the screw and cam to fail. The unsafe condition, if not addressed, could result in the loss of the ADG downlock mechanism functionality on aircraft touchdown which eliminates a critical power source for the aircraft, leaving the flight crew with the minimum flightdeck displays and difficulty controlling the aircraft.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–76.

(h) Exception to Transport Canada AD CF–2023–76

(1) Where Transport Canada AD CF–2023–76 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2023–76 refers to hours air time, this AD requires using flight hours.

(i) 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 manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-NYACO-COS@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; Transport Canada; or MHI RJ Aviation ULC's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *Fatin.R.Saumik@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) Transport Canada AD CF–2023–76, dated November 28, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–76, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-*

Consignesdenavigabilite.TC@tc.gc.ca. You may find this Transport Canada AD on the Transport Canada website at *tc.canada.ca/en/aviation.*

(4) 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.

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

Issued on April 17, 2024.

Victor Wicklund,

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

[FR Doc. 2024–08552 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1008; Project Identifier MCAI–2024–00080–T]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2023–02–13, which applies to certain Dassault Aviation Model FALCON 900EX airplanes. AD 2023–02–13 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2023–02–13, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2023–02–13 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). 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 June 7, 2024.

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–2024–1008; 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 material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu*. You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, 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–2024–1008.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–1008; Project Identifier MCAI–2024–00080–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 this 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 Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2023–02–13, Amendment 39–22320 (88 FR 8740, February 10, 2023) (AD 2023–02–13), for certain Dassault Aviation Model FALCON 900EX airplanes. AD 2023–02–13 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2022–0144, dated July 11, 2022 (EASA AD 2022–0144) (which corresponds to FAA AD 2023–02–13), to correct an unsafe condition.

AD 2023–02–13 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–02–13 to address reduced structural integrity of the airplane.

Actions Since AD 2023–02–13 Was Issued

Since the FAA issued AD 2023–02–13, EASA superseded AD 2022–0144

and issued EASA AD 2024–0035, dated January 31, 2024 (EASA AD 2024–0035) (referred to after this as the MCAI), for certain Dassault Aviation Model FALCON 900EX airplanes. The MCAI states that new or more restrictive airworthiness limitations have been developed.

The FAA is proposing this AD to address reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1008.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0035, which specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2022–0144, which the Director of the Federal Register approved for incorporation by reference as of March 17, 2023 (88 FR 8740, February 10, 2023).

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**.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would retain certain requirements of AD 2023–02–13. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2024–0035 already described, as proposed for incorporation by reference. Any differences with EASA AD 2024–0035 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to retain the IBR of EASA AD 2022–0144 and incorporate EASA AD 2024–0035 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0144 and EASA AD 2024–0035 through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0144 or EASA AD 2024–0035 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0144 or EASA AD 2024–0035. Service information required by EASA AD2022–0144 and EASA AD 2024–0035 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2024–1008 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 88 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2023–02–13 to be $7,650 (90 work-hours × $85 per work-hour).

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and

procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

(2) 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:

■ a. Removing airworthiness directive 2023–02–13, Amendment 39–22320 (88 FR 8740, February 10, 2023); and

■ b. Adding the following new airworthiness directive:

Dassault Aviation: Docket No. FAA–2024–1008; Project Identifier MCAI–2024–00080–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 7, 2024.

(b) Affected ADs

This AD replaces AD 2023–02–13, Amendment 39–22320 (88 FR 8740, February 10, 2023) (AD 2023–02–13).

(c) Applicability

This AD applies to Dassault Aviation Model FALCON 900EX airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2024–0035, dated January 31, 2024 (EASA AD 2024–0035).

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Terminating Action

This paragraph restates the requirements of paragraph (j) of AD 2023–02–13, with a new terminating action. Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0144, dated July 11, 2022 (EASA AD 2022–0144). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA 2022–0144, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2023–02–13, with no changes.

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0144 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2022–0144 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (3) of EASA AD 2022–0144 within 90 days after March 17, 2023 (the effective date of AD 2023–02–13).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0144 is at the applicable ''associated thresholds'' specified in paragraph (3) of EASA AD 2022–0144, or within 90 days after March 17, 2023 (the effective date of AD 2023–02–13), whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2022–0144 do not apply to this AD.

(5) The ''Remarks'' section of EASA AD 2020–0144 does not apply to this AD.

(i) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2023–02–13, with a new exception. Except as required by paragraph (j) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0144.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0035. Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2024–0035

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0035.

(2) Paragraph (3) of EASA AD 2024–0035 specifies revising ''the approved AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0035 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0035, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0035.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0035.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0035.

(m) 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 manager of the International Validation Branch, mail it to the address identified in paragraph (n) 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 EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Additional Information

For more information about this AD, contact Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email: *tom.rodriguez@faa.gov.*

(o) 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 [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2024–0035, dated January 31, 2024.

(ii) [Reserved]

(4) The following service information was approved for IBR on March 17, 2023 (88 FR 8740, February 10, 2023).

(i) European Union Aviation Safety Agency (EASA) AD 2022–0144, dated July 11, 2022.

(ii) [Reserved]

(5) For EASA AD 2024–0035 and EASA AD 2022–0144, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 17, 2024.

Victor Wicklund,

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

[FR Doc. 2024–08598 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–0948; Airspace Docket No. 24–ASW–9]

RIN 2120–AA66

Amendment of Class E Airspace; Dallas-Fort Worth, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Dallas-Fort Worth, TX. The FAA is proposing this action as the result of an airspace review conducted due to the amendment of the instrument procedures at Bourland Field, Fort Worth, TX—contained within the Dallas-Fort Worth, TX, Class E airspace legal description. This action will bring the airspace into compliance with FAA orders to support instrument flight rule (IFR) procedures.

DATES: Comments must be received on or before June 7, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–0948 and Airspace Docket No. 24–ASW–9 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instruction for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

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

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Bourland Field, Fort Worth, TX—contained within the Dallas-Fort Worth, TX, airspace legal description—to support IFR operations at these airports.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA

will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT post 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–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published subsequently in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface to within a 6.9-mile (increased from a 6.5-mile) radius of Bourland Field, Fort Worth, TX.

This action is the result of an airspace review conducted due to the amendment of the instrument procedures at Bourland Field to supports the IFR operations at this airport.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

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

* * * * *

ASW TX E5 Dallas-Fort Worth, TX [Amended]

Dallas-Fort Worth International Airport, TX
(Lat 32°53′50″ N, long 97°02′16″ W)
McKinney National Airport, TX
(Lat 33°10′37″ N, long 96°35′20″ W)
Ralph M. Hall/Rockwall Municipal Airport, TX
(Lat 32°55′50″ N, long 96°26′08″ W)
Mesquite Metro Airport, TX
(Lat 32°44′49″ N, long 96°31′50″ W)
Lancaster Regional Airport, TX
(Lat 32°34′39″ N, long 96°43′03″ W)
Point of Origin
(Lat 32°51′57″ N, long 97°01′41″ W)
Fort Worth Spinks Airport, TX
(Lat 32°33′54″ N, long 97°18′30″ W)
Cleburne Regional Airport, TX
(Lat 32°21′14″ N, long 97°26′02″ W)
Bourland Field, TX
(Lat 32°34′55″ N, long 97°35′27″ W)
Granbury Regional Airport, TX
(Lat 32°26′35″ N, long 97°49′17″ W)
Parker County Airport, TX
(Lat 32°44′47″ N, long 97°40′57″ W)
Bridgeport Municipal Airport, TX
(Lat 33°10′26″ N, long 97°49′42″ W)
Decatur Municipal Airport, TX
(Lat 33°15′15″ N, long 97°34′50″ W)

That airspace extending upward from 700 feet above the surface within a 30-mile radius of Dallas-Fort Worth International Airport; and within a 6.6-mile radius of McKinney National Airport; and within 1.8 miles each side of the 002° bearing from McKinney National Airport extending from the 6.6-mile radius to 9.2 miles north of the airport; and within a 6.3-mile radius of Ralph M. Hall/Rockwall Municipal Airport; and within 1.6 miles each side of the 010° bearing from Ralph M. Hall/Rockwall Municipal Airport extending from the 6.3-mile radius to 10.8 miles north of the airport; and within a 7-mile radius of Mesquite Metro Airport; and within a 6.6-mile radius of Lancaster Regional Airport; and within 1.9 miles each side of the 140° bearing from Lancaster Regional Airport extending from the 6.6-mile radius to 9.2 miles southeast of the airport; and within 8 miles northeast and 4 miles southwest of the 144° bearing from the Point of Origin extending from the 30-mile radius of Dallas-Fort Worth International Airport to 35 miles southeast of the Point of Origin; and within a 6.5-mile radius of Fort Worth Spinks Airport; and within 8 miles east and 4 miles west of the 178° bearing from Fort Worth Spinks Airport extending from the 6.5-mile radius to 21 miles south of the airport; and within a 6.9-mile radius of Cleburne Regional Airport; and within 3.6 miles each side of the 292° bearing from the Cleburne Regional Airport extending from the 6.9-mile radius to 12.2 miles northwest of airport; and within a 6.9-mile radius of Bourland Field; and within a 8.8-mile radius of Granbury Regional Airport; and within a 6.3-mile radius of Parker County Airport; and within 8 miles east and 4 miles west of the 177° bearing from Parker County Airport extending from the 6.3-mile radius to 21.4

miles south of the airport; and within a 6.3-mile radius of Bridgeport Municipal Airport; and within 1.6 miles each side of the 040° bearing from Bridgeport Municipal Airport extending from the 6.3-mile radius to 10.6 miles northeast of the airport; and within 4 miles each side of the 001° bearing from Bridgeport Municipal Airport extending from the 6.3-mile radius to 10.7 miles north of the airport; and within a 6.3-mile radius of Decatur Municipal Airport; and within 1.5 miles each side of the 263° bearing from Decatur Municipal Airport extending from the 6.3-mile radius to 9.2 miles west of the airport.

* * * * *

Issued in Fort Worth, Texas, on April 18, 2024.

Martin A. Skinner,

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

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1242

[Docket No. CPSC–2023–0037]

Notice of Availability and Request for Comments: Data Regarding Incidents Associated With Nursing Pillows

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule; availability of supplemental information; request for comment.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) published a notice of proposed rulemaking (NPR) in September 2023 to address the risk of death and injury associated with infant suffocations, entrapments, falls, and other hazards associated with nursing pillows. CPSC is announcing the availability of, and seeking comment on, details about incident data relevant to the rulemaking that are associated with infants and the use of nursing pillows. The Commission is also seeking comments on how a final rule should address nursing pillow covers.

DATES: Submit comments by May 23, 2024.

ADDRESSES: Submit comments, identified by Docket No. CPSC–2023–0037, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: To read background documents or comments regarding this proposed rulemaking, go to: *https://www.regulations.gov,* insert Docket No. CPSC–2023–0037 in the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Timothy Smith, Project Manager, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; email: *tsmith@cpsc.gov;* telephone: (301) 987–2557.

SUPPLEMENTARY INFORMATION: Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, in September 2023, the Commission published an NPR, Safety Standard for Nursing Pillows, to reduce the risk of death and injury associated with nursing pillows. 88 FR 65865 (Sept. 26, 2023).

A nursing pillow is any product intended, marketed, or designed to position and support an infant close to a caregiver's body while breastfeeding or bottle feeding. These products rest upon, wrap around, or are worn by a caregiver in a seated or reclined position. The Commission is considering how slipcovers (*i.e.,* removable nursing pillow covers) should be regulated as part of nursing pillows. For instance, should the definition of ''nursing pillow'' specifically state that a slipcover sold as part of the nursing pillow is included within definition of a nursing pillow? Additionally, slipcovers sold with the nursing pillows can consist of those that are only intended to fit over the nursing pillow to change its look, or it can contain buckles or straps needed to attach or wear the nursing pillow. Should the Commission distinguish between slipcovers that do or do not contain functional attachments such as buckles and straps? Manufacturers of nursing pillows often sell replacement slipcovers. Should these replacement slipcovers, sold by the original manufacturer of the nursing pillow, be included within the definition of ''nursing pillow''? The Commission invites public comments answering these questions and discussing how slipcovers should be regulated in the final rule.

In addition, the Commission is now making available incident reports underlying the data discussed in the NPR.[1] These reports have been redacted to protect personal information, confidential medical information, and other information protected from disclosure by section 6 of the CPSA. 15 U.S.C. 2055.

The NPR contains information about incidents from two databases: the Consumer Product Safety Risk Management System (CPSRMS)[2] and the National Electronic Injury Surveillance System (NEISS).[3] Staff

[1] The Commission voted 5–0 on April 16, 2024, to publish this document. Commissioners Feldman and Dziak voted to take other action to change the comment period from 30 to 60 days, if a majority supported the change, and if a majority did not support the change, to approve a 30-day comment period. No other Commissioner voted to change the 30-day comment period, so the comment period remains 30 days.

[2] CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports. A large portion of CPSRMS data consists of incident reports from consumer complaints, media reports, medical examiner or coroner reports, retailer or manufacturer reports (incident reports received from a retailer or manufacturer involving a product they sell or make), safety advocacy groups, law firms, and federal, state, or local authorities, among others. It also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes (ICD–10). The third major component of CPSRMS is the collection of in-depth follow-up investigation reports. Based on the incident reports, death certificates, or NEISS injury reports, CPSC field staff conduct IDIs (on-site, via telephone, or online) of incidents, deaths, and injuries, which are then stored in CPSRMS.

[3] NEISS is the source of the injury estimates; it is a statistically valid injury surveillance system.

searched these databases for fatalities and incidents associated with nursing pillows and involving infants up to 12 months old (where the age was known), reported to have occurred between January 1, 2010, and December 31, 2022. For this timeframe, staff identified 154 fatal and 34 nonfatal incidents reported to CPSC. The NPR included information about the hazard patterns of fatal and nonfatal incidents, such as infants' ages, hazard scenarios, nursing pillow/infant placement, and product-specific concerns.

Relevant data from CPSRMS include incident reports from medical examiners, consumers, death certificates, and manufacturers. Some of the incident data are obtained from 124 in-depth investigations (IDIs) conducted by CPSC. Among these IDIs, 122 involved fatal incidents, and two involved nonfatal incidents. Other incident data was reported by firms to CPSC under section 15(b) of the CPSA, 15 U.S.C. 2064(b), which included 13 non-fatal incidents. CPSC also relied on incidents received from the public and state and local government agencies as well as medical examiner/coroner reports, which included 24 fatal incidents and one nonfatal incident. In addition, the data includes information obtained from eight death certificates.

Data from NEISS contain incidents and injuries treated in U.S. hospital emergency departments. CPSC staff performed multiple searches consisting of a combination of product codes and narrative keyword searches to find nursing pillow incidents in NEISS. The first data search included all reports with the product code that includes nursing pillows (code 4050 Pillows excl. water pillows). The second data search looked for specific keywords [4] in the narrative field across all product codes. Subsequent searches included several infant-related product codes [5] and searches in the narrative field for keywords related to known manufacturer names.[6] Staff then analyzed the results and determined that an event was in-scope if the product involved was identified as a nursing pillow that played a contributing role in the incident. Staff also included events as in-scope only if the infant was up to 12 months of age, or age was unknown but the incident likely involved an infant based on the description of the incident. The data were extracted in January 2023. The Commission relied on 18 records of nonfatal incidents from NEISS, associated with nursing pillows, all involving injuries resulting from falls.

The Commission invites comments on the incident data and analysis of this data in the NPR. CPSC is making available for review and comment the incident reports relied upon and discussed in the NPR, to the extent allowed by applicable law, along with the associated IDIs. To obtain access to the data, submit a request to: *https://forms.office.com/g/jrUSbYnWGx.* You will then receive a website link to access the data for this rulemaking at the email address you provide. Information on how to submit comments and contact information for CPSC's Office of the Secretary are in the **ADDRESSES** section of this notice.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–08606 Filed 4–22–24; 8:45 am]

BILLING CODE 6355–01–P

NEISS injury data are gathered from emergency departments of about 100 hospitals, with 24-hour emergency departments and at least six beds, selected as a probability sample of all U.S. hospitals. The surveillance data gathered from the sample hospitals enable CPSC to make timely national estimates of the number of injuries associated with specific consumer products.

[4] Nurse pillo/nursi/feeding pillo/feed pillo/shape pillo/shaped pillo/support pillo/boppy/docka/dock a/atot/baby nest/flathead/flat head/pillow/pilow/feeding/bop.

[5] Code 1513 Playpens and play yards, code 1529 Portable cribs, code 1537 Bassinets or cradles, code 1542 Baby mattresses or pads, code 1543 Cribs, nonportable, code 1545 Cribs, not specified, code 1552 Cribs, nonportable or not specified, code 1562 Other soft baby carriers, code 4002 Bedding, not specified, code 4010 Mattresses, not specified, code 4082 Toddler beds, and code 9101 No clerical coding—retailer report.

[6] Pilo/pillo/bop/shape/shappe/nurs/loung/docka/dock a/atot/nest/tofoan/to foan/frida/brest frien/breast frien/bamibi/bambi/balboa/mombo/lat nurs/miracl/minky/kids n such/snuggle/tillyou/till you/maman/doc a/occo/leach/cuddle/podster/nogg/tummy/choice/elephant/horsesh/horse sho/donut/circular/plush/peanut/doc-a comfy/kaki/iblin/lyu/yumo/onr/majik/cheer/lovel/humble bee/humble-bee/graco/luna lul/ergob/ergo b/Infantin/chilling home/chillinghome/blublu/twinz/twin z/lansino/Beaba/MomCozy/miracle baby/Ingenuity/Babestellar/Babymoov/Kushies/nesting pill/ecohealth pill/Sustainable Baby/zzzpal/zzz pal/Feeding Friend.

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112, 1130, and 1243

[Docket No. CPSC–2023–0047]

Notice of Availability and Request for Comment: Data Regarding Incidents Associated With Infant Support Cushions

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule; availability of supplemental information; request for comment.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) published a notice of proposed rulemaking (NPR) in January 2024 regarding a rulemaking to address suffocation, entrapment, fall, and other hazards associated with infant support cushions. CPSC is announcing the availability of, and seeking comment on, details about incident data relevant to the rulemaking that are associated with infants and the use of infant support cushions.

DATES: Submit comments by May 23, 2024.

ADDRESSES: Submit comments, identified by Docket No. CPSC–2023–0047, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: To read background documents or comments regarding this proposed rulemaking, go to: *https://www.regulations.gov,* insert Docket No. CPSC–2023–0047 in the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Ashley Johnson, Project Manager, Directorate for Health Sciences, U.S.

Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 504–7872 email: *aajohnson@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Under this statutory direction, in January 2024 the Commission published an NPR, Safety Standard for Infant Support Cushions, to reduce the risk of death and injury associated with infant support cushions. 89 FR 2530 (Jan. 16, 2024).

An infant support cushion is defined in the NPR as ''an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone, or recumbent position.'' 89 FR 2544. This definition includes infant pillows, infant loungers, nursing pillows with a lounging function, infant props or cushions used to support an infant for activities such as ''tummy time,'' and other similar products. 89 FR 2530.

The Commission is now making available incident reports underlying the data discussed in the NPR, as described below.[1] These reports have been redacted to protect personal information, confidential medical information, and other information protected from disclosure by section 6 of the Consumer Product Safety Act. 15 U.S.C. 2055.

The NPR discussed information about incidents from two databases: the Consumer Product Safety Risk Management System (CPSRMS) [2] and the National Electronic Injury Surveillance System (NEISS).[3] CPSC staff searched these databases for fatalities, incidents, and concerns associated with infant support cushions and involving infants up to 12 months old, reported to have occurred between January 1, 2010, and December 31, 2022. The data for this timeframe pertained to at least 79 fatal and 124 nonfatal incidents reported to CPSC.[4] The NPR included information about the hazard patterns of fatal and nonfatal incidents such as infants' ages, hazard scenarios, infant support cushion/infant placement, and product-specific concerns. 89 FR 2532–34.

Relevant data from CPSRMS include incident reports from medical examiners, consumers, death certificates, and manufacturers. Some of the incident data relied on for the rulemaking were obtained from 83 in-depth investigations (IDIs) conducted by CPSC. Among these IDIs, 73 were fatal incidents and 10 were nonfatal incidents. The Commission also obtained information from reports submitted by consumers, medical examiners, and the Food and Drug Administration concerning five other fatal incidents and 58 nonfatal incidents involving falls (29 incidents), threatened asphyxiation (26 incidents), and one incident report each of limb entrapment, choking and near strangulation. 89 FR 2533.[5] Incident data has been redacted for personally identifiable information or confidential information, as required by law and any applicable confidentiality agreements.

The Commission also relied on data from NEISS that contains incidents and injuries treated in U.S. hospital emergency departments. One of these incidents resulted in a fatality. The Commission relied on 26 NEISS records associated with infant support cushions, as summarized in a spreadsheet of these NEISS incidents.

The Commission invites comments on the incident data and analysis of this data in the NPR. CPSC is making available for review and comment the incident reports relied upon and discussed in the NPR, to the extent allowed by applicable law, along with the associated IDIs. To obtain access to the data, submit a request to: *https://forms.office.com/g/AJ1JCDNuKD.* You will then receive a website link to access the data for this rulemaking at the email address you provide. Information on how to submit comments and contact information for CPSC's Office of the Secretary are in the **ADDRESSES** section of this notice.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–08605 Filed 4–22–24; 8:45 am]

BILLING CODE 6355–01–P

[1] The Commission voted 5–0 on April 16, 2024, to publish this document. Commissioners Feldman and Dziak voted to take other action to change the comment period from 30 to 60 days, if a majority supported the change, and if a majority did not support the change, to approve a 30-day comment period. No other Commissioner voted to change the 30-day comment period, so the comment period remains 30 days.

[2] CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports. A large portion of CPSRMS data consists of incident reports from consumer complaints, media reports, medical examiner or coroner reports, retailer or manufacturer reports (incident reports received from a retailer or manufacturer involving a product they sell or make), safety advocacy groups, law firms, and federal, state, or local authorities, among others. It also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes (ICD–10). The third major component of CPSRMS is the collection of in-depth follow-up investigation reports. Based on the incident reports, death certificates, or NEISS injury reports, CPSC Field staff conduct IDIs (on-site, via telephone, or online) of incidents, deaths, and injuries, which are then stored in CPSRMS.

[3] NEISS is the source of the injury estimates; it is a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of about 100 hospitals, with 24-hour emergency departments and at least six beds, selected as a probability sample of all U.S. hospitals. The surveillance data gathered from the sample hospitals enable CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

[4] The NPR listed 125 nonfatal incidents, but one of those incidents was a duplicate.

[5] As stated above, one incident reported in the NPR (a threatened asphyxiation) has been removed as a duplicate.

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 246

[Docket ID: DOD–2023–OS–0058]

RIN 0790–AL63

Stars and Stripes Media Organization

AGENCY: Assistant to the Secretary of Defense for Public Affairs, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: This rulemaking proposes to update authorities and responsibilities for the Stars and Stripes Media Organization (often abbreviated as Stripes) to reaffirm its editorial independence in providing media products not only to military service members and DoD civilian employees, but to U.S. veterans, families of veterans and current service members, and contractor personnel, particularly those serving overseas, based on changes in the consumption of news and information in a digital age. It additionally proposes to remove internal operational procedures of the Stars and Stripes Media Organization that do not require rulemaking under the Administrative Procedure Act.

DATES: Comments must be received by June 24, 2024.

ADDRESSES: You may submit comments, identified by docket number and/or Regulation Identifier Number (RIN) number and title, by any of the following methods:

- *Federal Rulemaking 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 and docket number or RIN 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: Kyle Combs, 703–695–6290.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statement of Need for This Rulemaking

This rulemaking update will clarify and reaffirm Stripes' authorities and responsibilities as the only DoD-authorized organization to provide First Amendment-type reporting and editorially independent media products for the benefit of the U.S. military community, including veterans, families of veterans and current service members, and contractor personnel, as well as current service members and DoD civilian employees, and remove those elements from the CFR that do not require rulemaking because they constitute internal management procedures. This update will also reflect the shift of Stripes from a print-first to digital-first media organization, as consumption of information has evolved in a digital age and media competition has increased. Stripes provides a reliable source of commercially available U.S. and world news and original news stories developed through first-hand reporting by Stripes staff from bases around the world that is accurate, fair, impartial, credible, and editorially independent of the military chain of command and military public affairs activities. By keeping its audience informed, Stripes provides news of interest to the U.S. military community that enables them to exercise their responsibilities of citizenship.

This rulemaking reaffirms Stripes operating as a nonappropriated fund instrumentality, a government entity established for military morale, welfare, and recreation of the U.S. military community that may both generate revenue and receive appropriated fund support consistent with its mission and applicable policy. Stripes is to be funded to the maximum extent possible through the sale and distribution of the newspapers, other products, authorized advertising, and other sources of revenue, as approved by the DoD and the Congress.

This rulemaking also reaffirms the Stripes Ombudsman position and purpose, in accordance with the Fiscal Years 1990–91 National Defense Authorization Act House Committee on Armed Services Report, which requested the establishment of the Ombudsman position and that the Ombudsman report to the DoD and annually to the House Armed Services Committee on the state of the free flow of information to the Armed Forces via Stripes. The ombudsman position defends the independence of Stripes on behalf of its readers by ensuring that the Stripes newsroom is free from command interference or censorship. The position ensures that the newsroom upholds accuracy, fairness, and independence.

B. Legal Authority

Section 113 of Title 10, U.S.C., provides the Secretary of Defense, subject to the direction of the President, authority, direction, and control over the DoD. 10 U.S.C. 191 and 192 provide authority to the Secretary of Defense to establish Defense Agencies and Field Activities to provide common services to the Military Departments and provide for their supervision when such action would be more effective, economical, or efficient. The Defense Media Activity is presently the Defense Field Activity to which Stripes belongs. Stripes is a DoD organization providing First Amendment-type reporting that allows for a free flow of news information so that service members in all Military Departments and Services may stay informed of current events and issues to support exercise of their responsibilities of citizenship, especially where commercial news sources have limited incentives to report or distribute. Funded partly with appropriated funds and partly with nonappropriated funds, Stripes operates as a nonappropriated fund instrumentality and supports the morale, welfare, and readiness of the U.S. military community by providing a reliable source of accurate, fair impartial, and credible news to its audience, consistent with 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness, and DoD Instructions 1015.08, ''DoD Civilian Employee Morale, Welfare, and Recreation (MWR) Activities and Supporting Nonappropriated Fund Instrumentalities (NAFI)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101508p.pdf*); 1015.10, ''Military Morale, Welfare, and Recreation (MWR) Programs'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101510p.pdf?ver=2019-04-08-125319-650*), and 1015.15, ''Establishment, Management, and Control of Nonappropriated Fund Instrumentalities and Financial Management of Supporting Resources'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101515p.pdf?ver=2019-04-08-125317-820*).

C. Regulatory History

This regulation, 32 CFR part 246, was previously published in the **Federal Register** (59 FR 19137) on April 22, 1994, and included DoD policy and internal procedures concerning the Stars and Stripes newspapers and business operations at the time. Since 1994, the regulation has had minor administrative updates, but does not presently reflect the changes in consumption of news and information in a digital age.

DoD is now proposing revising this regulation to reflect current policies concerning those portions of the Stripes mission discussed in this preamble. This revision also removes information that is not necessary for inclusion in the CFR, consistent with the Administrative Procedure Act. Internal policies and procedures will remain in DoD Directive (DoDD) 5122.11, ''Stars and Stripes (S&S) Newspapers and Business Operations (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/512211p.pdf*).

II. Impact of This Regulation

The updates to this rule are administrative in nature with no requirements of the public; therefore, the costs are nominal. Stripes content is to be provided at reasonable cost to the U.S. military community, comparable to the retail sales price of similar commercial newspapers throughout the United States, to ensure greatest access for its audience. Some advertiser-supported information is distributed to all readers at no cost. Stripes partially funds its mission in support of DoD through revenue-generating activities as a nonappropriated fund instrumentality. Stripes is also authorized appropriated funding, but Stripes is to be funded to the maximum extent possible through the sale and distribution of the newspapers, other products, authorized advertising, and other sources of revenue, as approved by the DoD and the Congress.

III. Regulatory Compliance Analysis

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

These Executive Orders direct agencies to assess all costs, benefits and available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety effects, distributive impacts, and equity). These Executive Orders emphasize the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated not significant, under section 3(f) of Executive Order 12866, as amended by Executive Order 14094. This rule revision highlights areas of public interest regarding Stripes' editorial independence, but it removes internal procedures that do not have external burden or implications. This rule does not have direct economic, environmental, public health, safety, distributive, or equity impacts.

B. Congressional Review Act (5 U.S.C. 801 et seq.)

Pursuant to the Congressional Review Act, this rule has not been designated a major rule, as defined by 5 U.S.C. 804(2). This rule does not have an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export market.

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

The Assistant to the Secretary of Defense for Public Affairs certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule only addresses the operations of Stripes, and it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to 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. This rule will not mandate any requirements for state, local, or tribal governments, and will not affect private sector costs.

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

It has been determined that this rule does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

F. Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that has Federalism implications, imposes substantial direct requirement costs on State and local governments, and is not required by statute, or has Federalism implications and preempts State law. This rule will not have a substantial effect on State and local governments.

G. Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or affects the distribution of power and responsibilities between the Federal government and Indian tribes. This rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 246, Government publications, Newspapers, and magazines.

■ Accordingly, 32 CFR part 246 is proposed to be revised to read as follows:

PART 246—STARS AND STRIPES MEDIA ORGANIZATION

Sec.

Authority: 10 U.S.C. 113, 136, 191–192.

§ 246.1 Purpose.

This part clarifies and reaffirms the Stars and Stripes (Stripes) Media Organization authorities and responsibilities to provide editorially independent media products and services.

§ 246.2 Definitions.

These terms and their definitions are for the purposes of this part.

(a) *Stars and Stripes Media Organization.* Stripes Media Organization is a DoD-authorized, multi-platform, global source of independent news and information organization serving the U.S. military community, especially overseas. It provides a reliable source of commercially available U.S. and world news and original news stories developed through first-hand reporting by Stripes' staff from bases around the world that is objective, credible, and editorially independent of the military chain of command and military public affairs activities. Stripes also covers news of local or host-country conditions relevant to the U.S. military community and other content of interest to their readership that generally receives only limited coverage, if any, from commercial sources.

(b) *Stripes media products and services.* Stripes media products and services are unofficial DoD multimedia products and services that provide current U.S. and world news, opinion, and other content of general interest to members of the U.S. military community. Products and services are provided to enhance morale, military readiness, and awareness of matters of particular interest to them as members of the U.S. military community, maintain their connection to American society, and assist them in continued exercise of their rights and obligations of citizenship.

(c) *Stripes Ombudsman.* The Stripes Ombudsman is a highly qualified independent news media professional hired from outside of the DoD to serve a three-year term. The Stripes Ombudsman independently advises the Stripes Publisher and senior editorial leaders, DoD leadership and congressional oversight authorities on matters relating to audience interests, journalistic practices, editorial interference, news management, or censorship.

(d) *Stripes Publisher.* The senior position in the Stripes Media Organization. This civilian government employee is a highly qualified independent news media professional who manages and controls the day-to-day business and financial, operational, and administrative activities, and provides editorial oversight of Stripes.

§ 246.3 Policy.

It is DoD policy that:

(a) The Stars and Stripes Media Organization publishes accurate, fair, impartial, and credible news and

information for the benefit and specific interest to the U.S. military community, especially those serving overseas, including DoD civilian and military personnel, contractor personnel, veterans, and their families.

(b) Stripes' content is to be provided at reasonable cost to the U.S. military community, comparable to the retail sales price of similar commercial news and information content throughout the United States, to ensure the greatest access for its audience.

(c) Stripes' editorial operations are independent of the military chain of command, military public affairs activities, or other external influences, and without censorship, inappropriate news management, or propaganda, but they fully comply with the policies and procedures that prevent the disclosure of information that is classified national security information or controlled unclassified information, would adversely affect national security, or clearly endanger the lives of U.S. personnel in accordance with the DoD authorities in paragraphs (a) through (e) of appendix A of this part and applicable laws, regulations, and Government-wide policies.

(d) Stripes' editorial policies and practices will be in keeping with journalistic standards of U.S. commercial news organizations of the highest quality, such as the Code of Ethics of the Society of Professional Journalists (available at *http://www.spj.org/ethicscode.asp*).

(e) Stripes' products and services may not advance a specific editorial position, point of view or particular interest, but will present a wide range of news and views, including coverage of U.S. political campaigns in an impartial, objective, and nonpartisan manner that does not imply endorsement of any candidate or political party.

(f) Stripes' products and services are unofficial and do not reflect the official views of, or endorsement by, the U.S. Government, the DoD, or subordinate command authorities.

(g) Stripes' reporters and editorial staff are DoD personnel authorized to gather and report news, good and bad, about the DoD and the U.S. military community. They may ask questions of DoD officials, gain help, have access, and attend gatherings or events available to reporters from the commercial media. Stripes reporters with access to DoD installations (because of their status as DoD personnel) may cover events or activities open to those with installation access even though commercial media may not have the same unescorted access; information published about or resulting from such events or activities is still subject to the requirements of paragraph (c) of this section.

(h) Although newsgathering is investigative by nature, Stripes is not an authorized investigative agency, such as a military criminal investigative organization, other DoD investigative body, or an office of Inspector General, and does not conduct official investigations on behalf of DoD. It may, however, report on such official DoD investigations, as well as investigations by outside organizations or commercial media in the public domain (*i.e.,* engage in investigative reporting).

(i) As DoD employees, the Stripes' news staff members must adhere to the DoD personnel policies that may not usually apply to journalists employed by commercial newspapers, including 5 CFR parts 2635 and 3601 and paragraphs (f) and (g) of appendix A of this part, as applicable, and all other applicable DoD policies and Federal laws and regulations as well as any applicable Status of Forces Agreements.

(j) Stripes partially funds its mission in support of DoD through revenue-generating activities as a nonappropriated fund instrumentality, a government entity established for morale, welfare, and recreation that may generate revenue and minimize the need for congressionally appropriated fund support. Stripes is to be funded to the maximum extent possible through the sale and distribution of news and information products, authorized advertising, printing services, and other sources of revenue, as approved by the DoD or Congress. While Stripes is authorized nonappropriated and appropriated funding, appropriated fund support is to be kept to a minimum level consistent with its mission but at levels provided for in paragraph (h) of appendix A of this part. Stripes also may be authorized appropriated funding for news and information production and free distribution to support members of the U.S military community deployed during armed conflict, exercises, or in contingency environments.

Appendix A to Part 246—Related Policies

The Stars and Stripes Media Organization is supported by the following policies:

(a) DoD Instruction 5200.01, ''DoD Information Security Program and Protection of Sensitive Compartmented Information (SCI)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/520001p.PDF*).

(b) DoD Instruction 5200.48, ''Controlled Unclassified Information (CUI)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/520048p.PDF*).

(c) DoD Manual 5200.01, Volume 1, ''DoD Information Security Program: Overview, Classification, and Declassification'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol1.pdf*).

(d) DoD Manual 5200.01, Volume 2, ''DoD Information Security Program: Marking of Information'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol2.pdf*).

(e) DoD Manual 5200.01, Volume 3, ''DoD Information Security Program: Protection of Classified Information'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/520001m_vol3.pdf*).

(f) DoD Directive 5500.07, ''Standards of Conduct'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/550007p.pdf*).

(g) Manual for Courts-Martial United States (2019 Edition) (available at *https://jsc.defense.gov/Portals/99/Documents/2019%20MCM%20(Final)%20(20190108).pdf*).

(h) DoD Instruction 1015.15, ''Establishment, Management, and Control of Nonappropriated Fund Instrumentalities and Financial Management of Supporting Resources'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101515p.pdf*).

Dated: April 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–08527 Filed 4–22–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2023–0868]

RIN 1625–AA01

Anchorage Regulations; Los Angeles and Long Beach Harbors, California

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend the regulations for Los Angeles and Long Beach Harbors. This action would amend Anchorages F and G, and update anchorage usage and communication requirements. The purpose of this proposed rule is to improve navigation safety by modifying Anchorage F and G to accommodate an increased volume of vessel traffic and larger vessels calling on the Ports of Los Angeles and Long Beach and alleviate vessels anchoring near a subsea pipeline. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before July 22, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0868 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Rubymar Sebastian-Echevarria at D11 Waterways, Coast Guard; telephone (571) 613–2930 or (206) 820–5620, email *D11-DG-D11-Waterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2023–0868 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

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

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

Public meeting. We do not plan to hold a public meeting but we will consider doing so if we determine from public comments that a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
OMB Office of Management and Budget
§ Section
U.S.C. United States Code

III. Background, Purpose, and Legal Basis

The Coast Guard proposes to amend Anchorages F and G in Los Angeles and Long Beach Harbors to improve navigation safety and update anchorage usage and communication requirements. The legal basis and authorities for this notice of proposed rulemaking are found in 46 U.S.C. 70006, 33 CFR 109.05, 33 CFR 1.05–1, and DHS Delegation No. 00170.1 Revision 01.3, which collectively authorize the Coast Guard to propose, establish, and define regulatory anchorage grounds. Under Title 33 of the Code of Federal Regulation (CFR) § 109.05, U.S. Coast Guard District Commanders are delegated the authority to establish anchorage grounds by the Commandant of the U.S. Coast Guard. The Coast Guard established Anchorage Grounds under Title 33 CFR CGFR 67–46, 32 FR 17728, Dec. 12, 1967, as amended by CGD11–04–005, 71 FR 15036, Mar. 27, 2006.

IV. Discussion of Proposed Rule

The Coast Guard proposes to amend the boundaries and anchorage requirements for Anchorages F and G in Los Angeles and Long Beach Harbors. Changes in global demand patterns and supply chain disruptions have contributed to port congestion and increased usage of Anchorages F and G. Due to economies of scale, vessels calling on the Ports of Los Angeles and Long Beach have increased in size and require more surface area for anchoring and maneuvering. Additionally, a subsea pipeline is located approximately less than one nautical mile from the anchorages. For these reasons, the Coast Guard proposes expanding the distance between anchorages and requiring vessels greater than 1600 gross tons to place their propulsion plants in standby and have a second anchor ready to let go when forecasted and/or observed wind speeds and gusts are 35 knots or greater. This proposed requirement is needed to prevent vessels from dragging anchor and to prevent harm to vessels, the port, and the environment. The proposed regulation would update port, pilot, and communication information to maintain proactive anchorage management.

The specific anchorage boundaries and amendments are described in detail in the proposed regulatory text at the end of the document.

V. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. A summary of our analyses based on these statutes or Executive orders follows.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been

reviewed by the Office of Management and Budget (OMB).

This proposed regulatory action determination is based on the need to maintain navigation safety within the port by amending the boundaries of Anchorages F and G and updating anchorage usage and communication requirements. The proposed action would not negatively impact navigation. Vessels would still be able to maneuver in, around and through anchorages.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. 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. While some owners or operators of vessels intending to transit the anchorage grounds may be small entities, for the reasons stated in section V.A. above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment to the docket at the address listed in the **ADDRESSES** section of this preamble. In your comment, explain why you think it qualifies and how and to what degree this proposed rule would economically affect it.

C. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

D. Federalism

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

The legal basis and authorities for this notice of proposed rulemaking are found in 46 U.S.C. 70006, 33 CFR 109.05, 33 CFR 1.05–1, and DHS Delegation No. 00170.1, which collectively authorize the Coast Guard to propose, establish, and define regulatory anchorage grounds. Therefore, this proposed rule is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

E. Unfunded Mandates

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 million (adjusted for inflation) or more in any one year. Although this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights).

G. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, (Civil Justice Reform), to minimize litigation, eliminate ambiguity, and reduce burden.

H. Protection of Children

We have analyzed this proposed rule under Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks). This proposed rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

I. Indian Tribal Governments

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

J. Energy Effects

We have analyzed this proposed rule under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

K. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

L. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves the amendment of anchorages. This proposed rule would be categorically excluded under paragraph L59(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration

supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

M. Protest Activities

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

List of Subjects in 33 CFR Part 110 Anchorage Grounds.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 110 as follows:

PART 110—Anchorage Regulations

■ 1. The authority citation for part 110 is revised to read as follows:

Authority: 33 U.S.C. 2071, 46 U.S.C. 70006, 70034; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Amend § 110.214, by revising and republishing paragraphs (a)(1)(i), (ii), (a)(2)(i)(B), (a)(3), (b)(6), (7), and (c)(2) to read as follows:

§ 110.214 Los Angeles and Long Beach harbors, California.

(a) * * *

(1) * * *

(i) Unless otherwise directed by the Captain of the Port Los Angeles—Long Beach, the Long Beach Port Pilots will assign all anchorages inside the federal breakwater. All anchorages outside (seaward) of the federal breakwater will be assigned by Vessel Traffic Service Los Angeles-Long Beach (VTS LA–LB). The master, pilot, or person in charge of a vessel must notify the Long Beach Pilots (for anchorages inside the federal breakwater) or VTS LA–LB (for anchorages outside the federal breakwater) of their intention to anchor, upon anchoring, and at least fifteen minutes prior to departing an anchorage. All anchorage assignments will be made as described in this part unless modified by the Captain of the Port.

(ii) Radio communications for port entities governing anchorages are as follows: VTS LA–LB, call sign ''San Pedro Traffic'', Channel 14 VHF–FM; Long Beach Port Pilots, call sign ''Long Beach Pilots'', Channel 12 VHF–FM.

* * * * *

(2) * * *

(i) * * *

(B) No vessel may anchor anywhere else within Los Angeles or Long Beach harbors (inside the federal breakwater) for more than 10 consecutive days unless extended anchorage permission is obtained from the Captain of the Port. In determining whether extended anchorage permission will be granted, consideration will be given, but not necessarily limited to: The current and anticipated demands for anchorage space within the harbor, the requested duration, the condition of the vessel, and the reason for the request.

* * * * *

(3) Other General Requirements.

(i) When at anchor, all commercial vessels greater than 1600 gross tons shall, at all times, have a licensed or credentialed deck officer on watch and maintain a continuous radio listening watch unless subject to one of the exemptions in this paragraph. The radio watch must be on CH–12 VHF–FM when anchored inside the federal breakwater, and on CH–14 VHF–FM when anchored outside the federal breakwater, except for unmanned barges; vessels which have less than 100 gallons of oil or fuel onboard regardless of how the fuel is carried; and other vessels receiving advance approval from the Captain of the Port.

(ii) When winds are forecasted and/or observed at 35 knots or greater (including wind gusts) vessels shall ensure their propulsion plant is placed in immediate standby and a second anchor, if installed, is made ready to let go. Vessels unable to comply with this requirement must immediately notify the Captain of the Port. In such case, the Captain of the Port may require additional precautionary measures, including but not limited to one or more tugs standing by to render immediate assistance.

* * * * *

(b) * * *

(6) Commercial Anchorage F (outside of Long Beach Breakwater). The waters southeast of the Long Beach Breakwater bounded by a line connecting the following coordinates:

	Latitude	Longitude
Beginning Point	33–43′ 6″ N	118–8′ 6″ W
Thence west to	33–43′ 6″ N	118–10′ 30″ W
Thence south/southeast to	33–42′ 12″ N	118–9′ 54″ W
Thence south/southeast to	33–40′ 54″ N	118–9′ 30″ W
Thence south/southeast to	33–38′ 36″ N	118–7′ 42″ W
Thence north/northeast to	33–40′ 42″ N	118–6′ 54″ W

And thence north/northwest to the beginning point.

(7) Commercial Anchorage G (outside of the Middle Breakwater). The waters south of the Middle Breakwater bounded by a line connecting the following coordinates:

	Latitude	Longitude
Beginning Point	33–43′ 6″ N	118–11′ 18″ W
Thence west to	33–43′ 6″ N	118–12′ 18″ W
Thence south/southwest to	33–42′ 24″ N	118–14′ 18″ W
Thence southeast to	33–40′ 48″ N	118–13′ 0″ W
Thence northeast	33–41′ 0″ N	118–12′ 18″ W
Thence east/northeast to	33–42′ 12″ N	118–11′ 36″ W

And thence north/northeast to the beginning point.

* * * * *

(c) * * *

(2) The geographic boundaries of each anchorage are contained in paragraph (b) of this section.

TABLE 110.214(c)

Anchorage	General location	Purpose	Specific regulations
A	Los Angeles Harbor	Commercial	Note a.
B	Long Beach Harbor	.....do	.....Do.
C	.....do	.....do	Notes a, g.
D	.....do	Commercial & Naval	Notes a, b, g.
E	.....do	Commercial	Note c.
F	Outside Breakwater	.....do	Notes c, d, g.
G	.....do	.....do	Notes c, d.
N	Los Angeles Harbor	Small Craft	Note e.
P	Long Beach Harbor	.....do	Note f.
Q	.....do	.....do	Notes c, g.

Notes:

a. Bunkering and lightering are permitted.

b. West of 118°–09′–48″ W priority for use of the anchorage will be given to commercial vessels over 244 meters (approximately 800 feet). East of 118°–09′–48″ W priority for use of the anchorage will be given to Naval and Public vessels, vessels under Department of Defense charter, and vessels requiring use of the explosives anchorage.

c. Bunkering and lightering are prohibited.

d. This anchorage is within a Regulated Navigation Area and additional requirements apply as set forth in 33 CFR 165.1109(E).

e. This anchorage is controlled by the Los Angeles Port Police. Anchoring, mooring and recreational boating activities conforming to applicable City of Los Angeles ordinances and regulations are allowed in this anchorage.

f. This anchorage is controlled by the Long Beach Harbor Master. Anchoring, mooring and recreational boating activities conforming to applicable City of Long Beach ordinances and regulations are allowed in this anchorage.

g. When the explosives anchorage is activated portions of this anchorage lie within the explosives anchorage and the requirements of *paragraph (d)* of this section apply.

* * * * *

Dated: April 16, 2024.

Andrew M. Sugimoto,

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

[FR Doc. 2024–08636 Filed 4–22–24; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 22–238; FCC 24–38; FR ID 214900]

Supporting Survivors of Domestic and Sexual Violence

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (''Commission'') seeks comment on additional action it can take to help survivors of domestic violence access safe and affordable connectivity, particularly in the context of connected car services which may be used to stalk, harass, and revictimize survivors of domestic violence.

DATES: Interested parties may file comments on or before May 23, 2024, and reply comments on or before June 24, 2024. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public, the Office of Management and Budget (OMB), and other interested parties on or before June 24, 2024. Written comments on the Initial Regulatory Flexibility Analysis (IRFA) in this document must have a separate and distinct heading designating them as responses to the IRFA and must be submitted by the public on or before May 23, 2024.

ADDRESSES: You may submit comments, identified by WC Docket No. 22–238, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.
- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. *See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Filing,* Public Notice, 35 FCC Rcd 2788 (2020), *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy*

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), please send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

FOR FURTHER INFORMATION CONTACT: For further information on this proceeding, contact Thomas Hastings, *Thomas.Hastings@fcc.gov,* of the Wireless Telecommunications Bureau, Competition & Infrastructure Policy Division, (202) 418–1343. For additional information concerning the Paperwork Reduction Act proposed information requirements contained in this document, send an email to *PRA@fcc.gov* or contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking (*FNPRM*), in WC Docket No. 22–238; FCC 24–38, adopted April 3, 2024, and released on April 8, 2024. The full text of the document is available for download at *https://docs.fcc.gov/public/attachments/FCC-24-38A1.pdf.*

Regulatory Flexibility Act: The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice-and-comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a

significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) concerning the possible impact of the rule and policy changes contained in this Notice of Proposed Rulemaking. Written public comments are requested on the IRFA. Comments must be by the deadlines for comments on this Notice of Proposed Rulemaking indicated in the **DATES** section of this document and must have a separate and distinct heading designating them as responses to the IRFA and must be filed in WC Docket No. 22–238.

Paperwork Reduction Act: This document contains proposed modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the general public and the Office of Management and Budget to comment on the information collection requirements. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Ex Parte Rules: This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, then the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with 47 CFR 1.1206(b). In proceedings governed by 47 CFR 1.49(f), or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Providing Accountability Through Transparency Act: The Providing Accountability Through Transparency Act, Public Law 118–9, requires each agency, in providing notice of a rulemaking, to post online a brief plain-language summary of the proposed rule. The required summary of this Notice of Proposed Rulemaking is available at *https://www.fcc.gov/proposed-rulemakings.*

Synopsis

I. Introduction

1. In this *FNPRM,* the Commission seeks comment on additional action we can take to help survivors of domestic violence access safe and affordable connectivity, particularly in the context of connected car services. Modern vehicles are frequently equipped with a suite of connectivity tools and features, such as hands-free communication, real-time location, and other connectivity services. While these services provide benefits to drivers and passengers when used as intended, news reports suggest that these services have also been used to stalk, harass, and revictimize survivors of domestic violence.

2. We seek comment on solutions to help ensure that domestic violence survivors need not choose between access to personal transportation or exposing themselves to threatening, stalking, or other harmful behavior by those who can access the car's data and connectivity. We seek comment on the types, as well as the frequency of use, of connected car services in the marketplace today. In addition, we ask whether changes to the Commission's rules implementing the Safe Connections Act (SCA) are needed to address the impact of connected car services on domestic violence survivors. Safe Connections Act of 2022, Public Law 117–223, 116 Stat. 2280 (Safe Connections Act or SCA). In November 2023, the Commission adopted a Report and Order implementing the Safe Connections Act. Supporting Survivors of Domestic and Sexual Violence et al., WC Docket No. 22–238, Report and Order, FCC 23–96 (Nov. 16, 2023) (*SCA Report and Order*). We also ask more broadly what steps connected car service providers can proactively take to protect survivors from being stalked, harassed, intimidated, or otherwise revictimized through the misuse of connected car services.

II. Background

3. Domestic violence and abusive relationships are a significant safety and public health issue that result in individual harm and societal costs that extend beyond the survivor. Domestic violence affects more than 12 million people every year, and an average of 24 people per minute are subject to physical violence or stalking by an intimate partner. Almost half of all women and men in the United States have experienced psychological aggression by an intimate partner in their lifetime (48.4% and 48.8%, respectively). The effects of domestic violence disproportionately impact women. In addition, domestic violence disproportionately impacts people of color, LGBTQ+ individuals, and other individuals who identify with historically marginalized demographics. Estimates of economic costs due to domestic violence are vast and encompass disruptions to education and work, among other aspects.

4. *Safe Connections Act.* In recognition of the harmful and lasting impact that domestic violence and related crimes have on survivors, Congress passed the SCA in November of 2022. In particular, Congress recognized the reality that survivors seeking to escape their abusers are often tethered to their abusers by technology—such as shared mobile service—and that these lingering connections present unique challenges for survivors seeking to maintain essential connectivity while distancing themselves from their abusers. In the SCA, Congress found that ''perpetrators of violence and abuse . . . increasingly use technological and communications tools to exercise control over, monitor, and abuse their victims,'' and that ''[c]ommunications law can play a public interest role in the promotion of

safety, life, and property'' with respect to these types of violence and abuse. The SCA further found that ''[s]afeguards within communications services can serve a role in preventing abuse and narrowing the digital divide experienced by survivors of abuse.'' Congress, through the SCA, sought to ensure that survivors can separate from abusers without losing independent access to their mobile service plans. To further that objective, Congress directed the Commission to adopt rules to implement the protections established in the SCA for survivors of domestic violence.

5. *SCA Report and Order.* In November 2023, the Commission adopted the *SCA Report and Order* implementing the Commission's obligations under the SCA to help survivors of domestic violence and related crimes to separate service lines from accounts shared with their abusers, protect the privacy of calls made by survivors to domestic-violence hotlines, and support survivors suffering from financial hardship. The Commission defined key terms in the SCA, such as what constitutes a ''covered provider'' subject to the Commission's new rules. As noted in the *SCA Report and Order,* multi-line shared mobile service contracts present challenges for survivors of domestic violence who seek to maintain essential connectivity while also distancing themselves from their abuser, because the abuser may be an account holder and thus able to monitor the survivor's calls, text messages, and device location. In adopting rules implementing the SCA, the Commission recognized that it can be difficult for the survivor to separate their mobile service line from their abuser when the plan is shared with and controlled by the abuser.

6. *Concerns of Misuse of Connected Car Applications by Abusers.* Connected cars bring a myriad of benefits that can improve conditions for drivers, pedestrians, and motorists in general. These benefits include helping to locate a vehicle in a parking lot and connecting promptly with first responders in an emergency without a phone. These features typically require the car to have wireless connectivity and to create and share location data. However, when these data and connectivity are in the wrong hands, they may be used to harm a survivor in—or attempting to leave—an abusive relationship. Indeed, recent reports suggest that connected cars can be ''weaponized'' against survivors, especially when survivors co-own or share a car with an abuser. For instance, connected cars co-owned or leased by both the abuser and survivor may allow the abuser to track the survivor using the car's location-based services. One news report suggests that survivors may have only limited ability to remove an abuser from their vehicle's data services and that connected car manufacturers may hesitate to act or abstain from acting altogether when the abuser has an ownership interest in the connected car with the survivor.

7. *FCC Letters and Responses.* In response to this public policy concern and Congress' directive in the SCA, in January 2024, Chairwoman Rosenworcel sent a series of letters to wireless service providers and to auto manufacturers to seek information and ask for their help in protecting domestic violence survivors. The letters to the wireless providers asked about existing connected car services, treatment of geolocation data from these services, current compliance with the SCA, and whether (and if so, how) the companies provide connected car services to consumers who are not subscribers to the company's wireless services. The letters to the auto manufacturers asked the companies for details about the connected car services they offer, any existing plans to support survivors' efforts to disconnect from abusers, and how the manufacturers handle consumers' geolocation data.

8. In their responses, as discussed further below, the wireless service providers noted their shared concerns about safeguarding survivors of domestic violence and affirmed that they are taking steps to implement the SCA. The auto manufacturers provided an overview of the functions and privacy features of their connected car services.

III. Discussion

9. We seek comment generally on the ways that connected car services are used and steps the Commission can take to help protect survivors of domestic violence from misuse of such services. First, based on the responses to the information requests sent by the Chairwoman, we describe and seek comment on our understanding of wireless service providers' and auto manufacturers' connected car service offerings. We also seek additional information on any other connected car services that are available. Next, we seek comment on whether changes to the Commission's rules implementing the SCA are necessary to address the impact of connected car services on domestic violence survivors. Finally, we seek comment on other actions we can take to help protect survivors using connected car services. In that regard, we seek comment on other potential sources of authority for Commission action and on how to encourage connected car service providers to take proactive steps to protect survivors against misuse of these services.

10. *The Connected Car Services Available Today.* The responses to Chairwoman Rosenworcel's information requests show that wireless service providers and auto manufacturers currently provide a range of connected car services in the marketplace. We seek additional information about how these services are offered to consumers.

11. One method for offering connected car services is through a wireless service provider. The wireless service providers' responses to the Chairwoman's information requests suggest that their offerings generally consist either of (1) services offered directly to consumers or (2) wholesale connectivity services offered to auto manufacturers or to the manufacturer's contracted third-party telematics service provider. For services offered directly to consumers, wireless service providers may enter into an agreement with a subscriber to add a line with an associated phone number to their wireless service contract for the connected car service. Subscribers typically access these services using an app and, in some cases, a separate device that plugs into their vehicle's control panel. The direct-to-subscriber services offer a range of features such as roadside assistance, navigation, and notification of required vehicle maintenance. Wireless service provider responses to the information requests suggest that some of these services also include the ability to track the vehicle's location remotely. Some wireless service providers also offer in-vehicle Wi-Fi services to consumers. When wireless service providers offer wholesale connectivity services, the providers may not have a direct contractual relationship with individual vehicle owners or lessees. Rather, they may contract directly with auto manufacturers via wholesale agreements or with other third parties to provide connectivity for a fleet of vehicles. We seek comment on our understanding of the connected car services offered by wireless service providers, and we seek additional information on any other features and capabilities not covered in this paragraph.

12. With respect to auto manufacturers' connected car services, the responses suggest that, when purchasing service from an auto manufacturer, the owner or lessee of a car typically enters into a service agreement with the auto manufacturer

for connected car services. A car owner typically accesses connected services on their mobile device through a manufacturer-provided app. Many auto manufacturers obtain the network connectivity to power these services by entering into contracts to access the wireless networks of wireless service providers or other third parties. The connected car services provided by auto manufacturers include a range of features such as the ability to start the vehicle or control the vehicle's climate control system remotely. Some services also include the ability to track the vehicle's location remotely. We seek comment on our understanding of the connected car services offered by auto manufacturers, and we seek additional information on any other features and capabilities not covered in this paragraph.

13. It appears that consumers—including domestic violence survivors—have varying levels of control of the data that connected car services generate, including remote vehicle location data. Responses to the information requests suggest that while some of the wireless service providers and auto manufacturers enable a survivor to turn off remote location tracking if the survivor becomes aware of being tracked by an abuser, not all companies currently provide that ability. For some connected car services, it appears that only a vehicle owner or lessee may disable tracking features on the connected car app absent a court order or other legal process. Some of the responses to the information requests indicate that the provider's connected car service gives notice to a driver that the car's location is being tracked. Other responses do not indicate whether the service offers this function. The responses to the information requests further indicate that information collected through connected car services may be shared with third parties in accordance with connected car service agreements. We seek further information on whether and how users, including both owners or lessees and nonowners or lessees, control access to their data for connected car services that are available today and on what information users receive about the tracking features of these services. To what extent do auto manufacturers and wireless service providers enable—or plan to enable—access controls for data associated with connected car services for owners and lessees and other vehicle users?

14. *Application of the SCA and the FCC's Implementing Rules to Connected Car Services.* We seek comment on what, if any, changes to our rules implementing the SCA could help to address the impact of connected car services on domestic violence survivors. A ''shared mobile service contract'' is defined under the SCA rules to mean ''a mobile service contract for an account that includes not less than two lines of service and does not include enterprise services offered by a covered provider. ''Lines of service,'' under the SCA rules, are those ''associated with a telephone number'' and include ''all of the mobile services associated with that line under the shared mobile service contract, regardless of classification, including voice, text, and data services.'' The SCA Report and Order makes clear that a ''line'' can apply to devices, ''such as tablets with no mobile capability, which only nominally have a line associated with a customer account,'' noting, for example, that ''a survivor may want to separate a line for a device in order to protect his or her location information from an abuser with access to the shared mobile account information.''

15. Line separation requirements apply, under the SCA rules, to ''covered providers.'' ''Covered providers'' are defined as providers of ''a private mobile service or commercial mobile service, as those terms are defined in 47 U.S.C. 332(d).'' ''Covered provider'' includes providers of mobile broadband-only or mobile text service that do not also offer mobile voice service, if such provider assigns a telephone number to a device. ''Covered provider'' also includes facilities-based mobile network operators and resellers/mobile virtual network operators (MVNOs).

16. Where the defined elements in the Commission's SCA rules are present, the obligations associated with line separations apply. The FCC's rules implementing the SCA thus could apply to connected car services that involve a ''shared mobile service contract'' offered by a ''covered provider'' as defined under the rules and would require a provider to respond to a valid request for a line separation. We seek comment on this position and the extent to which the FCC's existing SCA rules do not fully address concerns regarding the impact of connected car services on domestic violence survivors and whether changes to these rules would enable the Commission to better address these concerns.

17. As stated above, the definition of ''covered provider'' under the SCA rules includes providers both of commercial mobile service and private mobile service and also includes facilities-based mobile network operators and resellers/MVNOs. In the context of connected cars, wireless providers offer services directly to consumers and may enter into an agreement with a subscriber to add a line to their mobile service contract for the connected car service. Wireless providers also provide wholesale service to auto manufacturers, which in turn provide connectivity for consumers as a value-added service. Auto manufacturers enter into service agreements with owners and lessees of vehicles to provide them connected car services using, in many cases, the connectivity from the networks of wireless service providers. We view the broad scope of the ''covered provider'' definition as potentially including the connected car services that wireless service providers offer directly to consumers, and we highlight this view to assist efforts to implement the Commission's recently adopted rules under the SCA. Does the definition also include the service that auto manufacturers purchase wholesale and in turn offer to consumers? Does the definition of ''covered provider'' in the SCA rules need to be modified to account for additional use cases in order to better protect survivors, and if so, what revisions do commenters recommend? Would doing so be consistent with the policy objectives and authority of the SCA?

18. To what extent are auto manufacturers reselling mobile connectivity when providing connected car services? In clarifying that the SCA rules extend to MVNOs, the Commission noted in the SCA Report and Order that, for some MVNOs, ''the underlying facilities-based provider may have control over some parts of, or all of, the systems and infrastructure necessary to effectuate line separations.'' The Commission clarified that, in those cases, ''the MVNO should fulfill its obligations under the SCA and our rules through its contractual relationship with the underlying facilities-based provider, and may satisfy its obligations by utilizing the same procedures and processes the facilities-based provider makes available to its own customers.'' To the extent an MVNO controls any facilities or systems, such as customer care or billing, the Commission found that ''the obligations imposed by the SCA fall entirely upon the MVNO and not the underlying facilities-based provider.'' We seek comment on how these findings may apply in the context of connected car services offered by auto manufacturers. Do auto manufacturers have control over any systems or infrastructure necessary to effectuate a line separation under the SCA rules? Are these systems entirely controlled by the wireless service providers who

provide the connectivity for the services? Are they controlled or operated jointly?

19. Under the SCA, ''shared mobile service contract'' is defined to mean ''a mobile service contract for an account that includes not less than 2 consumers.'' The rules implementing the SCA provide that a ''shared mobile service contract'' means ''a mobile service contract for an account that includes not less than two lines of service'' and define ''lines of service'' to mean those lines associated with a telephone number. Connected car services generally involve a ''shared mobile service contract'' when the service is offered by a wireless service provider as an add-on to an existing wireless service agreement. Do connected car services offered by auto manufacturers also involve multiple lines of service? For example, if someone owns multiple cars from the same manufacturer and each of those cars has connected car service, would there be a ''shared mobile service contract'' for those services? Do connected car services use ''lines of service'' as contemplated under the SCA framework? The responses to the information requests suggest that some connected car services associate phone numbers with specific vehicles. Is that association typical for the majority of connected car services? If there are some connected car services that do not involve ''shared mobile service contracts'' and ''lines of service'' as currently defined by the Commission, are there ways that the Commission can revise these definitions, consistent with our authority under the SCA, to expand their scope and apply to connected car services? Would doing so be consistent with the policy objectives of and authority granted by the SCA? For example, to the extent connected car services are not currently encompassed in the Commission's definition of ''shared mobile service contract'' under our rules, does the language in the SCA definition that refers to ''an account that includes not less than 2 consumers'' suggest that we could extend the definition to a shared account (*e.g.,* co-owners or co-lessees of a vehicle) for connected car services?

20. To the extent that connected car services are—or could be—covered by the SCA, how would line separation requirements apply? Are there operational or technical issues that would affect implementation, including any unique challenges for small entities? For example, how would vehicle ownership affect implementation? Are vehicles typically owned on a shared basis by both members of a couple? We expect that, if a vehicle is under the sole ownership of an abuser, but is used by a survivor, the SCA rules would require separation of the connected car service line that is associated with that vehicle through the abuser's account. In these cases, what evidence and standards of proof would be needed from a survivor to separate the connected car service line? Currently, under the Commission's SCA rules, survivors seeking a line separation are required to submit documentation that verifies that an individual who uses a line under the shared mobile service contract has committed or allegedly committed a covered act against the survivor or an individual in the survivor's care. Would there be any reason to modify these evidentiary requirements for connected car services?

21. *Other Actions to Protect Survivors Using Connected Car Services.* Outside of the SCA, we seek comment on other authority the Commission could use and other steps the Commission could take to help prevent the misuse of connected car services. To the extent that connected car services are not covered by the SCA and Commission rules, are there other sources of authority the Commission could use to help address the misuse of these services? For example, could the Commission use its authority under other Title III provisions to adopt requirements that apply to the connected car services offered by wireless service providers and/or auto manufacturers?

22. Outside of formal Commission action, what steps can providers of connected car services take to prevent the misuse of connected car services in domestic violence situations? How can the Commission encourage providers to take such steps? What changes to the design and functionality of these services are needed to help protect survivors of domestic violence? In particular, we seek comment on what steps providers of connected car services could take to make it easier for survivors to turn off remote location tracking and other services that might enable abusers to track, control, or revictimize survivors. For example, for some connected car services it appears that only a vehicle owner or lessee may disable tracking features on the connected car app absent a court order. Should manufacturers permit their apps to allow multiple account holders so that survivors using a co-owned vehicle may access the app to turn off tracking features? How could companies change their policies to better respond to domestic violence situations? What other users or sets of users should be permitted to disable such features? Are there any risks that would arise if companies were to allow users other than the owner or lessee to disable any connected car services?

23. What are companies' policies, and how can they best ensure that survivors are protected in instances when survivors request, and companies make, changes to location tracking or other connected services? Where companies do permit survivors who are not the primary account holder to request changes (such as turning off location data for a connected car service), do companies automatically send notices to primary account holders? If so, do companies need to notify a primary account holder (who may be an abuser) about such changes? Should companies set a uniform waiting period between when the company receives a request from a survivor and when the company notifies a primary account holder? Could companies delay notice to primary account holders until the company has approved and processed such requests, or do the companies need to communicate with primary account holders prior to making changes?

24. Are there other ways to allow vehicle tracking for legitimate safety reasons (*e.g.,* driver safety or vehicle theft recovery) without making the tracking features accessible by abusers? Are there changes that automakers could make to alert unsuspecting survivors about tracking services that may be active in their vehicles? What other steps should auto manufacturers and wireless service providers consider to prevent the misuse of connected car services? Should they provide consumers with more information about the connectivity features, privacy controls, and other settings available in connected car services and apps? Should they develop more specific policies to address the misuse of connected car services in domestic violence situations? How can the Commission encourage auto manufacturers and wireless service providers to collaborate proactively with stakeholders to protect against misuse of connected car services?

25. *Promoting Digital Equity and Inclusion.* As noted earlier, the effects of domestic violence disproportionately impact women as well as people of color, LGBTQ+ individuals, and other individuals who identify with historically marginalized demographics. The Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or Tribal areas, women, LGBTQ+ persons, and others who are or

have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations and benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, we seek comment on how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority.

IV. Initial Regulatory Flexibility Analysis

26. As required by the Regulatory Flexibility Act of 1980, as amended, (RFA), the Federal Communications Commission (Commission) has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the Further Notice of Proposed Rulemaking (*FNPRM*). The Commission requests written public comments on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the *FNPRM.* The Commission will send a copy of the *Notice,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the *FNPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

27. Connectivity services in modern vehicles such as hands-free communication or find-your-car are intended to function as convenient tools for passengers and drivers. However, in the hands of an abuser, those same services can be used to stalk, harass, and intimidate survivors of domestic violence. In the *FNPRM,* the Commission seeks comment generally from small and other entities on the ways that connected car services are used and what further action the Commission can take to help protect domestic violence survivors from misuse of these services. First, based on the responses the Commission received to the information requests sent by the Chairwoman, the *FNPRM* describes and seeks comment on the Commission's understanding of wireless-service providers' and auto manufacturers' connected car service offerings. The *FNPRM* also seeks additional information on any other connected car services that are available in today's marketplace. Next, the *FNPRM* seeks comment on whether changes to the Commission's rules implementing the Safe Connections Act (SCA) are necessary to address the impact of connected car services on domestic violence survivors. Finally, the *FNPRM* seeks comment on other actions the Commission can take to help protect survivors using connected car services, other potential sources of authority for Commission action, and how best to encourage connected car service providers to take proactive steps to protect survivors against abuse of these services.

B. Legal Basis

28. The proposed action is authorized pursuant to sections 1, 4(i), 4(j), 254, 345, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 151, 154(i), 154(j), 254, 345, and 403; section 5(b) of the Safe Connections Act of 2022, Public Law 117–223, 136 Stat 2280; and section 904 of Division N, Title IX of the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182, as amended by the Infrastructure Investment and Jobs Act, Public Law 117–58, 135 Stat. 429.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Would Apply

29. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

30. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the Small Business Administration's (SBA) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 33.2 million businesses.

31. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2020, there were approximately 447,689 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

32. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicate there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number, there were 36,931 general purpose governments (county, municipal, and town or township) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts with enrollment populations of less than 50,000. Accordingly, based on the 2017 U.S. Census of Governments data, we estimate that at least 48,971 entities fall into the category of ''small governmental jurisdictions.''

33. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 594 providers that reported they were engaged in the provision of wireless services. Of these providers, the

Commission estimates that 511 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

34. *Satellite Telecommunications.* This industry comprises firms ''primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' Satellite telecommunications service providers include satellite and earth station operators. The SBA small business size standard for this industry classifies a business with $38.5 million or less in annual receipts as small. U.S. Census Bureau data for 2017 show that 275 firms in this industry operated for the entire year. Of this number, 242 firms had revenue of less than $25 million. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 65 providers that reported they were engaged in the provision of satellite telecommunications services. Of these providers, the Commission estimates that approximately 42 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, a little more than half of these providers can be considered small entities.

35. *Wireless Broadband Internet Access Service Providers (Wireless ISPs or WISPs).* Providers of wireless broadband internet access service include fixed and mobile wireless providers. The Commission defines a WISP as ''[a] company that provides end-users with wireless access to the internet[.]'' Wireless service that terminates at an end user location or mobile device and enables the end user to receive information from and/or send information to the internet at information transfer rates exceeding 200 kilobits per second (kbps) in at least one direction is classified as a broadband connection under the Commission's rules. Neither the SBA nor the Commission have developed a size standard specifically applicable to Wireless Broadband Internet Access Service Providers. The closest applicable industry with an SBA small business size standard is Wireless Telecommunications Carriers (except Satellite). The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees.

36. Additionally, according to Commission data on internet access services as of June 30, 2019, nationwide there were approximately 1,237 fixed wireless and 70 mobile wireless providers of connections over 200 kbps in at least one direction. The Commission does not collect data on the number of employees for providers of these services, therefore, at this time we are not able to estimate the number of providers that would qualify as small under the SBA's small business size standard. However, based on data in the Commission's *2022 Communications Marketplace Report* on the small number of large mobile wireless nationwide and regional facilities-based providers, the dozens of small regional facilities-based providers and the number of wireless mobile virtual network providers in general, as well as on terrestrial fixed wireless broadband providers in general, we believe that the majority of wireless internet access service providers can be considered small entities.

37. *Local Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Local Resellers. Telecommunications Resellers is the closest industry with a SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 207 providers that reported they were engaged in the provision of local resale services. Of these providers, the Commission estimates that 202 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

38. *Toll Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Toll Resellers. Telecommunications Resellers is the closest industry with a SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 457 providers that reported they were engaged in the provision of toll services. Of these providers, the Commission estimates that 438 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

39. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Providers of internet services (*e.g.,* dial-up ISPs) or Voice over Internet Protocol (VoIP) services, via client-supplied telecommunications connections are also included in this industry. The SBA small business size standard for this industry classifies firms with annual receipts of $35 million or less as small. U.S. Census Bureau data for 2017 show that there were 1,079 firms in this industry that

operated for the entire year. Of those firms, 1,039 had revenue of less than $25 million. Based on this data, the Commission estimates that the majority of ''All Other Telecommunications'' firms can be considered small.

40. *Automobile Manufacturing.* This U.S. industry comprises establishments primarily engaged in (1) manufacturing complete automobiles (*i.e.,* body and chassis or unibody) or (2) manufacturing automobile chassis only. The SBA small business size standard for this industry classifies firms having 1,500 employees or less as small. 2017 U.S. Census Bureau data indicate that 157 firms operated in this industry for the entire year. Of this number, 145 firms employed fewer than 100 employees. Therefore, the Commission estimates that the majority of manufacturers in this industry are small entities.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

41. The *FNPRM* seeks comment on the ways that connected car services are used and steps the Commission can take to help protect survivors of domestic violence from misuse of these services. The Commission states that the FCC's rules implementing the SCA apply to connected car services that involve a ''shared mobile service contract'' offered by a ''covered provider'' as defined under the rules and would require a provider to respond to a valid request for a line separation. The *FNPRM* seeks comment on the extent to which the FCC's existing SCA rules do not fully address concerns regarding the impact of connected car services on domestic violence survivors and whether changes to these rules would enable the Commission to better address these concerns. Outside of the SCA, the *FNPRM* seeks comment on other sources of authority the Commission can use to help address the misuse of connected car services.

42. While the *FNPRM* does not specifically propose new rules, the Commission does discuss application of the existing SCA rules in a new context and to potentially additional entities. The Commission seeks comment from small and other entities on whether any changes to the SCA rules are necessary. If the Commission ultimately decides to make any changes to the SCA rules in the connected car context, this could potentially result in additional costs, new or modified recordkeeping, reporting, or other compliance requirements for small and other providers. For example, the existing SCA rules require covered providers, within two business days of receiving a completed request from a survivor, to (1) separate the line of the survivor, and the line of any individual in the care of the survivor, from a shared mobile service contract, or (2) separate the line of the abuser from a shared mobile service contract. We seek comment on the impact to compliance for small and other entities as a result of rules reflecting a broader application of the SCA.

43. At present, the record does not include a detailed cost/benefit analysis that would allow us to quantify the costs of compliance for small entities, including whether it will be necessary for small entities to hire professionals to comply with any rules that may be adopted. Small and other entities are encouraged to quantify the costs and benefits of any reporting, recordkeeping, or compliance requirement that may be established in this proceeding. The Commission expects the comments it receives on its proposals, and the matters discussed in the *FNPRM* to include information addressing costs, benefits, and other matters of concern for small entities, which should help the Commission identify and better evaluate compliance costs and relevant issues for small entities before adopting final rules.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

44. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

45. The *FNPRM* considers alternative approaches for addressing the misuse of connected car services. It discusses application of the existing SCA rules in the connected car services context and seeks comment on whether any changes to the SCA rules are necessary to address these services. To the extent that connected car services are or could be covered by the SCA, the *FNPRM* seeks comment on how line separation requirements would apply. The *FNPRM* also asks whether there are operational or technical issues that would affect implementation, including for small entity providers. The *FNPRM* also seeks comment on an alternative, non-regulatory approach that would minimize potential burden and provide additional flexibility for connected car providers, including any small entity providers. The *FNPRM* seeks comment on how the Commission can encourage connected car service providers to voluntarily take steps to prevent the misuse of connected car services in domestic violence situations. In particular, the *FNPRM* seeks comment on what steps providers of connected car services could take to make it easier for survivors to turn off remote location tracking and other services that might enable abusers to track, control, or revictimize domestic violence survivors.

46. Additionally, to assist with the Commission's evaluation of the economic impact on small entities that may result from the actions and alternatives that have been proposed in this proceeding, the *FNPRM* seeks alternative proposals and requests information on the potential costs of such alternatives. The Commission expects to consider more fully the economic impact on small entities following its review of comments filed in response to the *FNPRM,* including costs and benefits information. Alternative proposals and approaches from commenters could help the Commission further minimize the economic impact on small entities. The Commission's evaluation of the comments filed in this proceeding will shape the final conclusions it reaches, the final alternatives it considers, and the actions it ultimately takes in this proceeding to minimize any significant economic impact that may occur on small entities from the final rules that are ultimately adopted.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

47. None.

V. Ordering Clauses

48. Accordingly, *it is ordered*, pursuant to the authority contained in sections 1, 4(i), 4(j), 254, 345, and 403 of the Communications Act of 1934, as amended; 47 U.S.C. §§ 151, 154(i), 154(j), 254, 345, and 403; section 5(b) of the Safe Connections Act of 2022, Public Law 117–223, 136 Stat 2280; and section 904 of Division N, Title IX of the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat. 1182, as amended by the Infrastructure Investment and Jobs Act, Public Law

117–58, 135 Stat. 429; that this *FNPRM* of Proposed Rulemaking *is adopted*.

49. *It is further ordered* that, pursuant to applicable procedures set forth in sections 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415, 1.419, interested parties may file comments on the *FNPRM* of Proposed Rulemaking on or before 30 days after publication in the **Federal Register**, and reply comments on or before 60 days after publication in the **Federal Register**.

50. *It is further ordered* that the Commission's Office of the Secretary *shall send* a copy of this *FNPRM* of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–08642 Filed 4–22–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R3–ES–2024–0022; FXES11110900000–245–FF09E21000]

Endangered and Threatened Wildlife and Plants; 12-Month Finding for Lake Sturgeon

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notification of petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12-month finding on a petition to list the lake sturgeon (*Acipenser fulvescens*) as an endangered or threatened species under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that listing the lake sturgeon as an endangered or threatened species is not warranted at this time. However, we ask the public to submit to us at any time any new information relevant to the status of the lake sturgeon or its habitat.

DATES: The finding in this document was made April 23, 2024.

ADDRESSES: A detailed description of the basis for this finding is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R3–ES–2024–0022. Supporting information used to prepare this finding is available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. Please submit any new information, materials, comments, or questions concerning this finding to the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Barbara Hosler, Regional Listing Coordinator, Midwest Regional Office, 517–351–6326, *barbara_hosler@fws.gov*. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding on whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (''12-month finding''). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted, but precluded by other listing activity. We must publish a notification of the 12-month finding in the **Federal Register**.

Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines ''species'' as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines ''endangered species'' as any species that is in danger of extinction throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and ''threatened species'' as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary of the Interior determines whether the species meets the Act's definition of an ''endangered species'' or a ''threatened species'' only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term ''foreseeable future'' extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. ''Reliable'' does not mean ''certain;'' it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

In conducting our evaluation of the five factors provided in section 4(a)(1) of the Act to determine whether lake sturgeon meets the Act's definition of an ''endangered species'' or ''threatened species,'' we considered and thoroughly evaluated the best scientific and commercial information available regarding the past, present, and future stressors and threats. We reviewed the petition, information available in our files, and other available published and unpublished information for the species. Our evaluation may include information from recognized experts; Federal, State, and Tribal governments; academic institutions; foreign governments; private entities; and other members of the public.

The species assessment form for the lake sturgeon contains more detailed biological information, a thorough analysis of the listing factors, a list of literature cited, and an explanation of why we determined that the species does not meet the Act's definition of an ''endangered species'' or a ''threatened species.'' To inform our status reviews, we completed a species status assessment (SSA) report for the lake sturgeon. The SSA report contains a thorough review of the taxonomy, life history, ecology, current status, and projected future status for the lake sturgeon. This supporting information can be found on the internet at *https://www.regulations.gov* under the Docket No. FWS–R3–ES–2024–0022.

Our analysis for this decision applied our current regulations, portions of which were last revised in 2019. Given that we proposed further revisions to these regulations on June 22, 2023 (88 FR 40764), we have also analyzed whether the decision would be different if we were to apply those proposed revisions. We concluded that the decision would have been the same if we had applied the proposed 2023 regulations. The analyses under both the regulations currently in effect and the regulations after incorporating the June 22, 2023, proposed revisions are included in our decision file for this action.

Previous Federal Actions

On May 23, 2018, we received a petition from the Center for Biological Diversity requesting that the lake sturgeon (*Acipenser fulvescens*) be listed as an endangered or threatened species rangewide, or in nine petitioned distinct population segments, and critical habitat be designated for this species under the Act. On August 15, 2019, we published a 90-day finding (84 FR 41691) that the petition contained substantial information indicating listing may be warranted for the species. A complaint was filed on February 20, 2020, by the Center for Biological Diversity, Fishable Indiana Streams for Hoosiers, Hoosier Environmental Council, and Prairie Rivers Network alleging that we failed to make a 12-month finding on the May 23, 2018, petition to list the lake sturgeon. As a result of the litigation, we have a court-ordered date of June 30, 2024, to deliver a 12-month finding to the **Federal Register**. This document constitutes our 12-month finding on the May 23, 2018, petition to list the lake sturgeon under the Act.

The petition also included nine potential distinct population segments (DPSs): Lake Superior, western Lake Michigan, Red River, Rainy Lake/Rainy River/Lake of the Woods, upper Mississippi River, Missouri River, Ohio River, Arkansas-White River, and the lower Mississippi River. After evaluating these populations under our 1996 Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act (DPS policy; 61 FR 4722, February 7, 1996), we found that each population is not discrete because it is not markedly separated from other populations of lake sturgeon, with evidence of migration and movement between each petitioned DPS and a population of lake sturgeon outside of the petitioned DPS. In addition, the Red River and Rainy Lake/Rainy River/Lake of the Woods petitioned DPSs are not discrete because they do not have significant differences in the control of exploitation, management of habitat, conservation status, or regulatory mechanisms from the connected lake sturgeon populations in Canada. For a more detailed discussion of our DPS analysis, please see the species assessment form.

Using the best available information, we determined that none of the petitioned DPSs meets the criteria for discreteness in our DPS policy. Because we did not find any of the petitioned DPSs to be discrete, we did not evaluate significance under the DPS policy. Therefore, we proceed with determining whether the lake sturgeon meets the Act's definition of an endangered or threatened species throughout all or a significant portion of its range.

Summary of Finding

Historically, lake sturgeon were widely distributed across the eastern and central United States and Canada. In Canada, the species was found within the Hudson Bay and Great Lakes watersheds and in rivers and lakes in Alberta, Saskatchewan, Manitoba, Ontario, and Quebec. In U.S. waters, they were distributed throughout the Great Lakes and their tributaries, the Mississippi River basin, as well as an isolated population in the Mobile River Basin in Alabama and Georgia. Although lake sturgeon occupy a reduced area today, they remain distributed in the four major North American drainages they occupied historically, including the Mississippi River basin, the Great Lakes, Hudson Bay, and the Mobile River Basin.

Sturgeon have a prehistoric appearance because of their large size, shark-like tails, and bony plate-armored covering. Lake sturgeon possess a torpedo-shaped body that is protected by five lateral rows of scutes (bony, diamond-shaped scales). Lake sturgeon are a long-lived fish, living to 150 years of age, and are late maturing, with males taking 12–20 years to mature and females taking 15–30 years. Two key habitat needs for lake sturgeon are access to suitable spawning and nursery habitat, and connectivity between all habitat types (Service 2023, pp. 12–13). Lake sturgeon travel from lakes and large rivers (foraging habitat) to tributaries (spawning habitat) to spawn, then the resulting lake sturgeon larvae will drift downstream to the mouth of

rivers (nursery habitat) until they are large enough to move to larger bodies of water. Spawning habitat generally consists of coarser substrate with interstitial spacing, water temperatures ranging from about 8–23.3 degrees Celsius (°C) (47–72 degrees Fahrenheit (°F)), and sufficient water flow in riverine habitat. Nursery habitat is similar, defined by riverine habitat with both fine sediment and coarser substrates, sufficient water flow, appropriate water temperatures, and food availability. To complete its life cycle, lake sturgeon need spawning, nursery, and adult foraging habitat to be connected and accessible. These habitat needs are also essential to supporting natural recruitment and adult abundance of life sturgeon. Generally, if spawning and nursery habitat are accessible, then natural recruitment will occur, which in turn will increase adult abundance.

For lake sturgeon populations to be resilient, they need a healthy demography (*i.e.,* stable or positive growth rates), habitat that provides connectivity to allow for gene flow among subpopulations, and sufficient habitat quality and quantity to support healthy individuals. For a lake sturgeon population to be considered demographically healthy, it needs a minimum of 750 total spawning adults and successful spawning and recruitment that occurs in most years. Lake sturgeon need widespread, naturally recruiting, abundant populations for redundancy. Additionally, lake sturgeon need genetic, behavioral, and ecological diversity across their range to have sufficient representation to adapt to future environmental change.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to lake sturgeon, and we evaluated all relevant factors under the five listing factors, including any regulatory mechanisms and conservation measures addressing these threats. The primary threats affecting the lake sturgeon's biological status are dams, barriers, and climate change (Service 2023, pp. 14–15, 17–22). Dams and barriers occur across the lake sturgeon's range and can block access to spawning and nursery habitat, stopping lake sturgeon from completing their life cycle, thus making this the most significant threat to the species.

We focused on the potential effects that warming water temperatures, as a result of climate change, could have on the lake sturgeon (Service 2023, pp. 24–25, 121–125). Warming water temperatures could have negative effects on the species by changing the timing of spawning runs and decreasing available habitat if waters get too warm. Warming water temperatures could also have a positive effect by increasing growth rate and creating habitat out of areas that were previously too cold. Other threats we considered in our analysis, but did not find to rise to a major species-level impact, include water quality degredation and pollution, disease and predation, recreational fishing, illegal harvest, effects of lamprey control, invasive species, loss of genetic diversity, and genetic risks from stocking. For more information on our analysis of these threats, see the SSA report (Service 2023, pp. 13–44).

The primary conservation measure for the lake sturgeon is stocking of captive-reared lake sturgeon. Stocking efforts occur across much of the lake sturgeon's range and have brought areas back from extirpation and bolstered the resiliency of existing populations (Service 2023, pp. 44–110). Other conservation measures we considered in our analysis include restoring connectivity of habitat through dam removal, creation of fish passages, habitat restoration, and invasive and non-native species eradication and control programs. Restoration of connectivity and habitat can have significant positive effects on lake sturgeon, but these benefits are more localized or benefit certain populations.

During the late 1800s and early 1900s, commercial harvest severely reduced the abundance of lake sturgeon while the construction of dams and channelization and dredging reduced the amount and accessibility of spawning and nursery habitat. By the late 1900s, lake sturgeon harvest was, and remains, heavily regulated and monitored by State agencies, effectively removing the threat of overharvest (Service 2023, pp. 30–42). While the threat dams pose to the species remains across the species' range, reducing access to spawning and nursery habitat, there have been significant efforts to recover the lake sturgeon. Stocking programs have helped to reintroduce or supplement populations of the lake sturgeon across much of its range, including six of eight representation units in the United States and three of four designatable units in Canada, providing increased resiliency for populations that are stocked (Service 2023, pp. 44–110). Along with stocking, restoration of connectivity has improved the ability of populations to recover naturally, such as in the Red River of the North (Service 2023, pp. 79–84). Due to the significant ongoing conservation and management efforts across the range of the species, areas that are being managed are trending positively and have increased resiliency compared to past decades (Service 2023, pp. 44–110). In addition, although abundance has been drastically reduced, highly and moderately resilient populations are still widely distributed, providing sufficient redundancy for the species rangewide (Service 2023, pp. 110–113).

Overall, lake sturgeon representation has been reduced from historical levels, but the species still maintains a moderate to high level of representation in multiple ways (Service 2023, pp. 113–116). While genetic diversity has been lost in the southernmost part of the range due to extirpations, the species has generally maintained a high level of genetic diversity. In addition, lake sturgeon may have some inherent phenotypic plasticity to respond to stressors. Lake sturgeon may have the ability to adapt to warming climates and can thrive in many different ecological settings. The primary reason representation has been reduced from historical levels is because the widescale construction of dams has reduced the ability of lake sturgeon to move up tributaries to spawn. However, lake sturgeon have a high level of adaptability to local changes and environmental conditions. Therefore, although dams have reduced representation from historical levels, the lake sturgeon currently has a sufficient level of representation to adapt to environmental changes (Service 2023, pp. 113–116).

In summary, the lake sturgeon has many highly and moderately resilient populations distributed throughout its range that provide sufficient redundancy for the species and the adaptive capacity to withstand near-term and long-term changes to the environment. Thus, after assessing the best available information, we conclude that the lake sturgeon is not in danger of extinction throughout all of its range.

Therefore, we proceed with determining whether the lake sturgeon is likely to become endangered within the foreseeable future throughout all of its range. We carried three major influences into our future condition analysis: dams, stocking, and climate change. We considered other influences and conservation efforts described in the SSA report, but we identified these three influences as having the highest likelihood of a potentially significant, species-wide impact into the future.

We do not anticipate the number of dams to change significantly across the range of the species in the future, meaning the effects of dams on the lake

sturgeon at the species level will likely remain similar to the current level of effects (Service 2023, pp. 117–118). While we expect dams and barriers to continue to have a significant negative effect on the lake sturgeon, we expect the stocking programs occurring in six of eight representation units in the United States and three of four designatable units in Canada to continue until management objectives are met; see the species assessment form and SSA report for management objectives (Service 2023, pp. 121–122). These representation and designatable units are generally trending upwards, largely because of conservation efforts. Due to a strong, long-term commitment to reestablishment and supplementation efforts by States and Tribes, we expect these efforts to continue until such time that they are no longer necessary. Overall, we expect lake sturgeon populations that are currently trending upward to continue to trend upward in the future, improving resiliency and redundancy for the species. The species current condition and positive trends from ongoing conservation efforts support species' viability in the face of environmental stochasticity and potential catastrophic events.

There is much uncertainty regarding how the lake sturgeon will respond to changes in habitat due to climate change. However, because of the species' relatively wide thermal tolerance, ability to move, and ability to adjust spawning phenology, the lake sturgeon shows a high degree of adaptability to climate change, although that adaptability will likely be limited by its ability to access suitable habitats. Overall, we expect representation in the future to remain similar to the current condition and remain sufficient to adapt to environmental changes.

In summary, the lake sturgeon is projected to have: (1) increased resiliency in populations with ongoing conservation efforts, (2) highly and moderately resilient populations distributed throughout its range that provide sufficient redundancy for the species, and (3) the adaptive capacity to withstand near-term and long-term changes to the environment. After assessing the best available information, we conclude that the lake sturgeon is not likely to become endangered within the foreseeable future throughout all of its range.

We also evaluated whether the lake sturgeon is endangered or threatened in a significant portion of its range. We evaluated four portions (*i.e.,* all analysis units that are currently functionally extirpated or have low overall resiliency and designatable units in a remnant status, the Hudson Bay drainage, the Atlantic drainage, and the Gulf of Mexico drainage) and did not find them to be significant because they are not large geographic areas relative to the range of the species as a whole and they do not constitute habitat of high quality or unique value relative to the remaining portions of the range of lake sturgeon. Because we did not find any portion to be significant, we did not evaluate whether any portion is in danger of extinction either now or within the foreseeable future. Therefore, we did not find any portions of the lake sturgeon's range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion, either now or within the foreseeable future. Thus, after assessing the best available information, we conclude that the lake sturgeon is not in danger of extinction in a significant portion of its range now, or within the foreseeable future.

After assessing the best available information, we concluded that the lake sturgeon is not in danger of extinction or likely to become in danger of extinction within the foreseeable future throughout all of its range or in any significant portion of its range. Therefore, we find that listing the lake sturgeon as an endangered species or threatened species under the Act is not warranted. A detailed discussion of the basis for this finding can be found in the lake sturgeon species assessment form and other supporting documents on *https://www.regulations.gov* under Docket No. FWS–R3–ES–2024–0022 (see **ADDRESSES**, above).

Peer Review

In accordance with our July 1, 1994, peer review policy (59 FR 34270; July 1, 1994) and the Service's August 22, 2016, Director's Memo on the Peer Review Process, we solicited independent scientific reviews of the information contained in the lake sturgeon SSA report. The Service sent the SSA report to nine independent peer reviewers and received three responses. Results of this structured peer review process can be found at *https://www.regulations.gov* under Docket No. FWS–R3–ES–2024–0022. We incorporated the results of these reviews, as appropriate, into the SSA report, which is the foundation for this finding.

New Information

We request that you submit any new information concerning the taxonomy of, biology of, ecology of, status of, or stressors to the lake sturgeon to the person listed above under **FOR FURTHER INFORMATION CONTACT**, whenever it becomes available. New information will help us monitor this species and make appropriate decisions about its conservation and status. We encourage local agencies and stakeholders to continue cooperative monitoring and conservation efforts.

References Cited

A list of the references cited in this document is available on the internet at *https://www.regulations.gov* under Docket No. FWS–R3–ES–2024–0022 in the species assessment form, or upon request from the person listed above under **FOR FURTHER INFORMATION CONTACT**.

Authors

The primary authors of this document are the staff members of the Species Assessment Team, Ecological Services Program.

Signing Authority

Martha Williams, Director of the U.S. Fish and Wildlife Service, approved this action on March 12, 2024, for publication. On April 16, 2024, Martha Williams authorized the undersigned to sign the document electronically and submit it to the Office of the Federal Register for publication as an official document of the U.S. Fish and Wildlife Service.

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Madonna Baucum,

Regulations and Policy Chief, Division of Policy, Economics, Risk Management, and Analytics of the Joint Administrative Operations, U.S. Fish and Wildlife Service.

[FR Doc. 2024–08567 Filed 4–22–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 240410–0104]

RIN 0648–BM68

Fisheries Off West Coast States; West Coast Salmon Fisheries; Measures To Keep Fishery Impacts Within the Conservation Objective for the California Coastal Chinook Salmon

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would implement a set of management measures recommended by the Pacific Fishery Management Council (Council) to ensure fishery impacts on California Coastal (CC) Chinook salmon, which are listed as threatened under the Endangered Species Act, remain within the conservation objective in the Council's Pacific Coast Salmon Fishery Management Plan (Salmon FMP). Under the proposed rule, management tools (*e.g.,* trip limits (also known as landing and possession limits) and inseason management) consistent with the provisions of the Salmon FMP would be used to provide greater certainty in avoiding exceedances of the conservation objectives for CC Chinook salmon.

DATES: Comments on this proposed rule must be received on or before May 23, 2024.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0009.* You may submit comments on this document, identified by NOAA–NMFS–2024–0009, by the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and type NOAA–NMFS–2024–0009 in the Search box (note: copying and pasting the FDMS Docket Number directly from this document may not yield search results). Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Shannon Penna, Fishery Management Specialist, at 562–980–4239 or *Shannon.Penna@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The ocean salmon fisheries in the exclusive economic zone (EEZ) (3–200 nautical miles; 5.6–370.4 kilometers) off Washington, Oregon, and California are managed under the Salmon FMP. The Salmon FMP and implementing regulations govern the development at the spring (March and April) Council meetings each year of annual management measures. Management measures for the salmon fisheries are developed annually because the abundance of the salmon stocks in the fishery can fluctuate significantly from one year to the next and information about annual stock abundance does not become available until early in each year (January–early March).

The commercial and recreational salmon fisheries off northern California and southern Oregon target healthy or abundant stocks of Chinook and coho salmon, but may incidentally encounter Endangered Species Act (ESA)-listed CC Chinook salmon and other ESA-listed species. The Salmon FMP includes harvest controls that are used to manage salmon stocks sustainably. The Salmon FMP also requires that the Council manage fisheries consistent with ''consultation standards'' for stocks listed as endangered or threatened under the ESA for which NMFS has issued biological opinions. NMFS has issued biological opinions for every ESA-listed salmon species impacted by the fisheries governed by the Salmon FMP and reminds the Council of requirements (*i.e.,* consultation standards) to maintain consistency with those opinions in its annual guidance letter to the Council regarding development of the annual ocean salmon management measures. To limit the effects of CC Chinook salmon, ocean salmon fisheries are managed to avoid exceeding a conservation objective for that stock.

The CC Chinook salmon Evolutionarily Significant Unit (ESU) has been listed as threatened under the ESA since 1999. The conservation objective for CC Chinook salmon is described in the Salmon FMP. Management of the fishery that avoids exceedance of the conservation objective has been analyzed in a series of biological opinions (most recently, an opinion issued in 2023), and has been determined to avoid jeopardizing the ESU (NMFS 2000; McInnis 2005; NMFS 2023; NMFS 2024). As described in these consultations, the data are insufficient for developing an ESU-specific conservation objective for CC Chinook salmon. Thus, NMFS has relied on a surrogate, Klamath River fall-run Chinook Salmon (KRFC), to evaluate and limit impacts on CC Chinook salmon in ocean salmon fisheries. The conservation objective is an ocean harvest rate (HR) on age-4 KRFC of 0.16. In its 2024 biological opinion, NMFS confirmed that managing fisheries to avoid exceeding this conservation objective would avoid jeopardy to CC Chinook.

From 2018 to 2022, the fishery HR on age-4 KRFC significantly exceeded 0.16 with an average of 0.28. Actions (*e.g.,* adjustments to ocean management models to account for these high catch rates and managing to a lower rate than the conservation objective) proved insufficient to avoid exceedance and the fisheries continued to exceed the conservation objective for CC Chinook salmon as well as impact limits on other California Chinook salmon stocks. The recent increases in the post-season KRFC age-4 ocean HR from 2018 through 2021 suggests that the level of impacts on CC Chinook salmon have likely increased.

For 2023, the Council considered additional measures to avoid another exceedance of the CC Chinook conservation objective. However, in response to record low forecasts for KRFC and Sacramento fall-run Chinook salmon, the Council ultimately recommended the closure of commercial and recreational salmon fisheries off the coast of California for 2023, and NMFS approved this closure. The management measures for the 2023–2024 ocean salmon fishing season include the potential use of landing and possession limits in the commercial salmon troll fishery and bag limits in the recreational salmon fishery for the March and April 2024 fisheries, should salmon abundance forecasts for 2024 and Council discussion support use of those measures. The projected KRFC age-4 ocean HR of 0.003 for the 2023–24 management measures, with the fishery closures off California, resulted from a low number of encounters of KRFC salmon in fisheries north of California.

The Council continued to explore measures that could be taken to manage the commercial salmon troll fishery to address the source of the high catch rates of KRFC and stay within the conservation objective, thereby not exceeding the conservation objective for CC Chinook salmon. At the November 2023 Council meeting, the Council adopted a set of management measures to ensure that the CC Chinook salmon conservation objective is not exceeded. The management measures are intended to ensure the fishery does not exceed the conservation objective for CC

Chinook by implementing management tools (*e.g.,* landing and possession limits, an overall allowable harvest level, inseason management) consistent with the provisions of the Salmon FMP.

Measures To Achieve Conservation Objectives for California Stocks of Chinook Salmon

The proposed fishery management measures are designed to ensure that the post-season ocean HR for age-4 KRFC does not exceed the conservation objective of 0.16. These measures would apply to the ocean salmon fisheries between the Oregon/California border and Pigeon Point, California.

The management measures included in this rule are focused on the ocean salmon fisheries off the coast of California (*i.e.,* California Klamath Management Zone, Fort Bragg, San Francisco, and Monterey management areas) for the following reasons:

1. The majority of the KRFC harvest (and assumed impacts on CC Chinook salmon) in the ocean occurs in this area;
2. The age-4 ocean HR for KRFC in this area has consistently exceeded pre-season projections in recent years;
3. Contact-rate-per-unit-effort in this area has exceeded projections in recent years;
4. The fisheries in this area have been managed primarily through season controls such as time and area restrictions (as opposed to use of landing and possession limits and/or quota management);
5. Time and area restrictions in this area have not been effective in controlling harvest of KRFC (and assumed impacts on CC Chinook salmon) in recent years; and,
6. Ocean fisheries in other areas that impact KRFC routinely implement the same or similar management measures as described in these measures for a similar purpose.

The rule would require implementation of measures used in salmon fisheries elsewhere on the West Coast to ensure fisheries in the affected area do not exceed the conservation objective for CC Chinook salmon. Historically, fisheries in the area described above have been managed by setting seasons and bag limits. In addition, for this fishery there was no overall limit on harvest or inseason management. The Salmon FMP contemplates that the Council and NMFS will use a range of management tools to ensure the fisheries are managed to avoid exceeding all limits for stocks caught in the various management areas along the West Coast (FMP Chapter 6). These management tools (*e.g.,* management boundaries, seasons, quotas, minimum harvest lengths, fishing gear restrictions, and recreational day bag limits) are available to manage ocean fisheries each season, once the allowable ocean harvests and the basis for allocation among user groups have been determined. New information on the fisheries and salmon stocks also may require other adjustments to the management measures.

Under the proposed set of management measures, annual management measures for the fisheries in the area described above will both be designed pre-season and managed inseason to stay within the objective. NMFS may apply, and the Council may recommend, a buffer to the conservation objective to account for management error and reduce the potential for exceeding the conservation objective, this buffer would be developed based on the percent error of the pre-season projected HR (as compared to the post-season HR) occurring over the most recent 5 years and other relevant factors. Fishery managers will compute an allowable harvest level of Chinook salmon for the year consistent with the conservation objective (including the buffer described above, if applicable). Using the allowable harvest level and projected effort, managers will determine landing and possession limits pre-season to ensure that the fishery does not exceed the allowable harvest level. The fishery will be monitored inseason and actions will be taken as needed to prevent the fisheries from exceeding the annual harvest level. We expect that this multilayered conservative approach (*i.e.,* a buffer, fishery output control, and inseason actions) will ensure that the fisheries remain within the pre-season projection and adhere to the CC Chinook salmon conservation objective.

This proposed rule will also update regulations to 50 CFR 660.405 and 660.410. In § 660.405, the term ''possess'' was added to provide consistency to other prohibitions throughout the regulations. With the new regulation requiring submission of fish tickets within 24 hours of landing, the addition of the term ''possess'' will ensure that fishers are not confused about the requirements related to the timing of catch and retention, possession, or landings. Also, in addition to the new management measures at § 660.410, this proposed rule would revise paragraph (c) by adding the abbreviation KRFC to address several new occurrences of KRFC that did not exist before.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the Salmon FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

There are no relevant Federal rules that may duplicate, overlap, or conflict with this action.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant adverse economic impact on a substantial number of small entities.

For purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 220.2). A business primarily engaged in commercial fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. This standard applies to all businesses classified under North American Industry Classification System (NAICS) code 11411 for commercial fishing, including all businesses classified as commercial finfish fishing (NAICS 11411), commercial shellfish fishing (NAICS 114112), and other commercial marine fishing (NAICS 114119) businesses (50 CFR 200.2; 13 CFR 121.201).

This proposed rule would directly affect the West Coast commercial troll salmon fishery. Using the Socioeconomic Assessment of the 2022 Ocean Salmon Fisheries (chapter IV) of the Review of 2022 Ocean Salmon Fisheries Stock Assessment and Fishery Evaluation Document for the Pacific Coast Salmon FMP the most recent year of complete fishing data (2022), had 563 distinct commercial vessels land fish caught in Washington, Oregon, and California. The total coastwide ex-vessel value was $22.2 million with California achieving $17.1 million, Oregon $3.2 million, and Washington $1.8 million. No vessel met the threshold to be considered a large entity as defined above. The preliminary number of vessel-based ocean salmon recreational

angler trips taken on the West Coast in 2022 was 264,200. All of those charter businesses that are impacted are small entities. Because all of the affected entities are small, the management measures in this proposed rule are not expected to place small entities at a significant disadvantage to large entities.

Because businesses have been harvesting over the conservation objective for over 5 years (table 1), this regulation which is intended to bring catch levels back down to the conservation objective (0.16 HR on age-4 KRFC), is expected to impose negative economic effects on small businesses relative to the last 5 years. The proposed action does not change the management objectives for CC Chinook, it is designed to ensure that the fisheries do not exceed the objective using management and tools that are allowed under the Salmon FMP. The effects are not quantifiable with available resources on the timeline needed to implement this rule to achieve conservation objectives. However, NMFS invites comments on this proposed rule with information about costs to small entities.

TABLE 1—ESTIMATES OF OCEAN HARVEST RATES OF AGE-4 KRFC SALMON PRE- AND POSTSEASON IN RECENT YEARS

Year	Preseason age-4 harvest rate forecast	Post-season age-4 harvest rate estimate	Pre/post for years >16%
2017	0.03	0.04	0.75
2018	0.12	0.24	0.05
2019	0.16	0.36	0.44
2020	0.09	0.23	0.39
2021	0.11	0.28	0.39
2022	0.10	0.38	0.26

NMFS believes that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared. This proposed rule contains revisions to a collection-of-information requirement subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act. This rule revises the existing requirements for the collection of information 0648–0433 by adding a requirement for submission of fish tickets within 24 hours of landing. Public reporting burden for fish ticket submission is estimated to average 0 hours because the submission will already be required by the California Code of Regulations.

A formal section 7 consultation under the ESA was initiated for the Salmon FMP. In a biological opinion dated February 29, 2024, NMFS determined that fishing activities conducted under the Salmon FMP and its implementing regulations are not likely to jeopardize the continued existence of any endangered or threatened species under the jurisdiction of NMFS or result in the destruction or adverse modification of critical habitat.

This proposed rule was developed after meaningful consultation and collaboration with the tribal representative on the Council.

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

Dated: April 15, 2024.

Samuel D. Rauch III,

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

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indians—lands, Recreation and recreation areas, Reporting and recordkeeping requirements, Treaties.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 660 as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.405, revise paragraphs (a)(1) and (a)(2) to read as follows:

§ 660.405 Prohibitions.

(a) * * *

(1) Take and retain, or possess, or land salmon caught with a net in the fishery management area, except that a hand-held net may be used to bring hooked salmon on board a vessel.

(2) Fish for, or take and retain, or possess, any species of salmon:

(i) During closed seasons or in closed areas;

(ii) While possessing on board any species not allowed to be taken in the area at the time;

(iii) Once any catch limit is attained;

(iv) By means of gear or methods other than recreational fishing gear or troll fishing gear, or gear authorized under § 660.408(k) for treaty Indian fishing;

(v) In violation of any action issued under this subpart; or,

(vi) In violation of any applicable area, season, species, zone, gear, daily bag limit, or length restriction.

* * * * *

■ 3. In § 660.410, revise paragraph (c) and add paragraph (d) to read as follows:

§ 660.410 Conservation objectives, ACLs, and de minimis control rules.

* * * * *

(c) *De minimis control rules.* Klamath River fall Chinook (KRFC) and Sacramento River fall Chinook salmon have the same form of *de minimis* control rule described in the FMP, which allows for limited fishing impacts when abundance falls below S_{MSY}. The control rule describes maximum allowable exploitation rates at any given level of abundance. The annual management measures may provide for lower exploitation rates as needed to address uncertainties or other year-specific circumstances. The *de minimis* exploitation rate in a given year must also be determined in consideration of the following factors:

(1) The potential for critically low natural spawner abundance, including considerations for substocks that may fall below crucial genetic thresholds;

(2) Spawner abundance levels in recent years;

(3) The status of co-mingled stocks;

(4) Indicators of marine and freshwater environmental conditions;

(5) Minimal needs for tribal fisheries;

(6) Whether the stock is currently in an approaching overfished condition;

(7) Whether the stock is currently overfished;

(8) Other considerations, as appropriate; and

(9) Exploitation rates, including *de minimis* exploitation rates, must not jeopardize the long-term capacity of the stock to produce maximum sustained yield on a continuing basis. NMFS expects that the control rule and associated criteria will result in decreasing harvest opportunity as abundance declines and little or no opportunity for harvest at abundance levels less than half of MSST.

(d) *Salmon Fisheries Affecting California Coastal Chinook.* Salmon fisheries affecting this ESA-listed stock are managed to meet the conservation objective described in FMP table 3–1.

(1) The annual specifications and management measures will include an allowable harvest level expressed in numbers of fish for these fisheries that is projected, using the Klamath Ocean Harvest Model and Sacramento Harvest Model, to ensure fisheries do not exceed the conservation objective. To determine the allowable harvest level, the Council and NMFS may use a harvest rate that is lower than the conservation objective (*i.e.,* harvest rate of 0.16) in order to address the potential for exceeding the objective in a particular year. The lower harvest rate will be determined in two steps.

(i) In the first step, NMFS and the Council will calculate the average percent error for the previous 5 years, and apply the average percent error to the conservation objective. Only positive percent error will be applied because the intent is to keep the post-season harvest rate below 0.16.

(ii) In the second step, other relevant factors affecting the preseason assessment of the age-4 KRFC harvest rate will be considered, such as revisions to the fishery management models used to estimate the preseason Chinook catch, environmental indicators relevant to the status of KRFC, constraints on fisheries under consideration for the areas and months with greatest impacts to KRFC Chinook, and the lower harvest rate may be modified based on these factors.

(2) The annual specifications and management measures will include the following management measures to ensure fisheries affecting California Coastal Chinook do not exceed the allowable harvest level.

(i) Landing and possession limits will be used in the commercial troll fisheries to keep fishery catch within the allowable harvest level. Landing and possession limits will be set for periods not to exceed 1 week. Landing and possession limits may vary from one calendar month to the next but will be the same for periods within the same calendar month.

(ii) A percentage of the allowable harvest level (*i.e.,* trigger) that will require consideration of inseason action to ensure that the allowable harvest level is not exceeded will be set through the annual management measures.

(iii) For the first 2 years after the promulgation of this rule in which salmon fishery occur in the EEZ off the California coast, inseason actions will only be used to further restrict harvest (*i.e.,* reduce landing limits, reduce time/area, and close the fishery when the allowable harvest level is projected to have been met).

(3) Electronic fish tickets must be submitted within 24 hours of landing to the California Department of Fish and Wildlife. Fish tickets must be submitted in accordance with the requirements of the applicable state regulations.

(4) NMFS will implement inseason actions as described in § 660.409, following processes described in that section, as needed to ensure catch in the fishery does not exceed the allowable harvest level and will close areas and seasons upon reaching the allowable harvest limit.

[FR Doc. 2024–08368 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[RTID 0648–XD632]

Fisheries of the Exclusive Economic Zone Off Alaska; Essential Fish Habitat Amendments

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

ACTION: Notification of availability of fishery management plan amendments; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) submitted amendment 127 to the Fishery Management Plan (FMP) for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI), amendment 115 to the FMP for Groundfish of the Gulf of Alaska (GOA), amendment 56 to the FMP for BSAI King and Tanner Crabs, amendment 17 to the FMP for the Salmon Fisheries in the exclusive economic zone (EEZ) Off Alaska, and amendment 3 to the FMP for Fish Resources of the Arctic Management Area (amendments) to the Secretary of Commerce for review. If approved, these amendments would revise the FMPs by updating the description and identification of essential fish habitat (EFH) and updating information on adverse impacts to EFH based on the best scientific information available. These amendments are intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the FMPs, and other applicable laws.

DATES: Comments on the amendments must be received no later than June 24, 2024.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2023–0160, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter [NOAA–NMFS–2023–0160] in the Search box (note: copying and pasting the FDMS Docket Number directly from this document may not yield search results). Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.
- *Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the amendments, maps of the EFH areas, and the Environmental Assessment (the analysis) prepared for this action may be obtained from *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Megan Mackey, 907–586–7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each regional fishery management council submit any FMP amendment it

prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary). The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP amendment, immediately publish a notice in the **Federal Register** announcing that the amendment is available for public review and comment. The Council has submitted these amendments to the Secretary for review. This notice announces that proposed amendment 127 to the FMP for Groundfish of the BSAI (BSAI Groundfish FMP); proposed amendment 115 to the FMP for Groundfish of the GOA (GOA Groundfish FMP); proposed amendment 56 to the FMP for BSAI King and Tanner Crabs (Crab FMP); proposed amendment 17 to the FMP for the Salmon Fisheries in the EEZ Off Alaska (Salmon FMP); and proposed amendment 3 to the FMP for Fish Resources of the Arctic Management Area (Arctic FMP) are available for public review and comment.

The Council prepared the FMPs under the authority of the Magnuson-Stevens Act. Regulations governing U.S. fisheries and implementing the FMPs appear at 50 CFR parts 600, 679, and 680. Section 303(a)(7) of the Magnuson-Stevens Act requires that each FMP describe and identify EFH, minimize to the extent practicable the adverse effects of fishing on EFH, and identify other measures to encourage the conservation and enhancement of EFH. Section 3(10) of the Magnuson-Stevens Act defines EFH as ''those waters and substrate necessary to fish for spawning, breeding, feeding, or growth to maturity.'' Implementing regulations at 50 CFR 600.815 list the EFH contents required in each FMP and direct councils to conduct a complete review of all EFH information at least once every 5 years (referred to here as ''the 5-year review'').

The Council developed the amendments as a result of new scientific information made available through the 5-year review that began in 2019 (2023 5-year review) and adopted the amendments in December 2023. The 2023 5-year review is the Council's fourth review of EFH in the FMPs. Prior 5-year reviews were completed in 2005, 2012, and 2018. The Council recommended amendments to the description and identification of EFH in the FMPs with new information and improved mapping as described in the draft EFH 5-year Summary Report for the 2023 5-year review. The Council also recommended updates to EFH information based on the best available information in the Summary Report. The Council recommended updates to EFH for all FMPs except for the Scallop FMP because no new information is available to update EFH descriptions for scallops.

The amendments would make the following changes to the FMPs:

- *BSAI Groundfish FMP, GOA Groundfish FMP, Crab FMP, and Arctic FMP:* update EFH descriptions and maps, including up to EFH Level 3 information on habitat-related vital rates (see 50 CFR 600.815(a)(1)(iii)(A)). Add or revise the EFH text descriptions and add or replace the maps for—
  - 41 species or complexes in the BSAI Groundfish FMP;
  - 46 species or complexes in the GOA Groundfish FMP;
  - all five species in the Crab FMP; and
  - all three species in the Arctic FMP.
- *Salmon FMP:* replace the distribution maps for all five species with the EFH maps.
- *BSAI Groundfish FMP, GOA Groundfish FMP, and Crab FMP:* changes based on the updated information for fishing effects (FE) to reflect updates to the FE model, analysis, and evaluation.
- *BSAI Groundfish FMP, GOA Groundfish FMP, Crab FMP, and Arctic FMP:* revise the EFH appendices where conservation recommendations for non-fishing activities are described.
- *BSAI Groundfish FMP, GOA Groundfish FMP, and Crab FMP:* revise prey species descriptions for two species of BSAI sharks, BSAI pollock, GOA Pacific cod, and BSAI red king crab.
- *BSAI Groundfish FMP, GOA Groundfish FMP, Crab FMP, and Arctic FMP:* revise EFH appendices with updated research and information needs.

NMFS is soliciting public comments on the proposed amendments through the end of the comment period (see **DATES**). All relevant written comments received by the end of the applicable comment period will be considered by NMFS in the approval/partial approval/disapproval decision for the amendments and addressed in the response to comments in the final decision. Comments received after end of the applicable comment period will not be considered in the approval/partial approval/disapproval decision on the amendments. To be considered, comments must be received, not just postmarked or otherwise transmitted, by the last day of the comment period (see **DATES**).

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

Dated: April 18, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08629 Filed 4–22–24; 8:45 am]

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Notices

Federal Register
Vol. 89, No. 79
Tuesday, April 23, 2024

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

Food Safety and Inspection Service

[Docket No. FSIS–2024–0006]

Notice of Request To Renew an Approved Information Collection: Requirements To Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, FSIS is announcing its intention to renew an approved information collection regarding requirements for official establishments to notify FSIS of adulterated or misbranded product, prepare and maintain written recall procedures, and document certain Hazard Analysis and Critical Control Point (HACCP) plan reassessments. There are no changes to the existing information collection. The approval for this information collection will expire on September 30, 2024.

DATES: Submit comments on or before June 24, 2024.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2024–0006. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: For access to background documents or comments received, call 202–720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

SUPPLEMENTARY INFORMATION:

Title: Requirements To Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments.

OMB Number: 0583–0144.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled.

FSIS is requesting renewal of an approved information collection regarding requirements for official establishments to notify FSIS of adulterated or misbranded product, prepare and maintain written recall procedures, and document certain HACCP plan reassessments. There are no changes to the existing information collection. The approval for this information collection will expire on September 30, 2024.

The regulations at 9 CFR 418.2, 418.3 and 417.4(a)(3) require establishments to notify FSIS that they have shipped or received adulterated or misbranded product in commerce, prepare and maintain written recall procedures, and document HACCP plan reassessments. Accordingly, FSIS requires three information collection activities under these regulations.

First, FSIS requires that official establishments notify the appropriate District Office that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. Industry representatives of official establishments may notify the District Office directly, notify local FSIS inspection personnel in receiving establishments, or may use FSIS Form 5720–16, *Industry Report of Adulteration,* to notify FSIS that an adulterated or misbranded meat, meat food, poultry, or poultry product was received from or shipped into commerce by the official establishment. The form is available as a paper form and digitally in the Public Health Information System (PHIS).

Second, FSIS requires that establishments prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by the establishment for use should it become necessary for the establishment to remove product from commerce. These written recall procedures have to specify how the establishment will decide whether to conduct a product recall, and how the establishment will affect the recall should it decide that one is necessary.

Finally, FSIS requires that establishments document each reassessment of the establishment's HACCP plans. FSIS requires establishments to reassess their HACCP plans annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary.

FSIS has made the following estimates as part of an information collection assessment.

Estimate of burden: The public reporting burden for this collection of information is estimated to average .232 hours per response.

Respondents: Official meat and poultry products establishments.

Estimated annual number of respondents: 6,300.

Estimated average number of responses per respondent: 6.8.

Estimated annual number of responses: 42,900.

Estimated total annual burden on respondents: 9,960.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the method 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, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.usda.gov/forms/electronic-forms,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

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Paul Kiecker,

Administrator.

[FR Doc. 2024–08628 Filed 4–22–24; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–65–2023]

Foreign-Trade Zone (FTZ) 125; Authorization of Production Activity; Grand Design RV, LLC; (Motor Homes); Middlebury, Indiana

On December 19, 2023, Grand Design RV, LLC submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 125H in Middlebury, Indiana.

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 (88 FR 90164, December 29, 2023). On April 17, 2024, 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: April 17, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–08603 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD888]

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will

hold its Main Hawaiian Islands (MHI) Deep 7 Bottomfish (BF) Risk of Overfishing (P*) Working Group (WG), MHI Social, Economic, Ecological, and Management WG to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The meetings will be held on May 7, 2024. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The Western Pacific Fishery Management Council (Council) will hold its Main Hawaiian Islands (MHI) Deep 7 Bottomfish (BF) Risk of Overfishing (P*) Working Group (WG), MHI Social, Economic, Ecological, and Management (SEEM) WG meetings will be held in a hybrid format with in-person and remote participation (Google Meets) options available for the members and the public. In person attendance for members and public will be hosted at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813. Instructions for connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

Council address: Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Contact Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The MHI Deep 7 P* WG will meet on Tuesday, May 7, from 9 a.m. to 12 p.m., MHI Deep 7 SEEM WG will meet on Tuesday, from 1 p.m. to 4 p.m. All times listed in HST.

Public Comment periods will be provided in the agendas. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the MHI Deep 7 Bottomfish P* Working Group

Tuesday, May 7, 2024, 9 a.m.–12 p.m. (Hawaii Standard Time)

1. Welcome and Introductions
2. Recommendations from previous Council meetings
3. Overview of the P* process
4. Report on 2023 Benchmark Stock Assessment for the MHI Deep 7
5. Working group scoring session
   a. Assessment information
   b. Uncertainty characterization
   c. Stock status
   d. Productivity and susceptibility
6. General Discussion
7. Public Comment
8. Summary of scores and P* Recommendations

Schedule and Agenda for the MHI Deep 7 Bottomfish SEEM Working Group

Tuesday, May 7, 2024, 1 p.m.–4 p.m. (Hawaii Standard Time)

1. Introductions
2. Overview of the SEEM process
3. Scoring of the SEEM Dimensions and Criteria Scores
   a. Social
   b. Economic
   c. Ecological
   d. Monitoring
   e. Management Uncertainty
4. Finalizing the SEEM scores
5. Public Comment
6. Summary of scores and SEEM Recommendations

Special Accommodations

These meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: April 18, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08652 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD891]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The MAFMC will hold a public meeting (webinar) of its Spiny Dogfish Advisory Panel. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will be held on Thursday, May 9, 2024, from 5 p.m. to 7:30 p.m.

ADDRESSES: Webinar connection information will be posted to the calendar prior to the meeting at *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The main purpose of the meeting is for the Advisory Panel (AP) to create a Fishery Performance Report that includes advisor input on specifications and management measures for spiny dogfish. While a management track assessment was used in 2023 to set 2024–2026 specifications, multi-year specifications are reviewed each year. The MAFMC will consider the Fishery Performance Report later in 2024 when 2025 spiny dogfish specifications are reviewed. Public comments will also be taken.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: April 18, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08654 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD835]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Port of Nome Modification Project in Nome, Alaska

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

ACTION: Notice; issuance of incidental harassment authorization.

SUMMARY: NMFS has received a request from the U.S. Army Corps of Engineers (USACE) for the reissuance of a previously issued incidental harassment authorization (IHA) with the only

change being effective dates. The initial IHA authorized take of 10 species of marine mammals, by Level B harassment only, incidental to construction activities associated with the Port of Nome Modification Project in Nome, Alaska. The project has been delayed by 1 year and none of the work covered in the initial IHA has been conducted. The initial IHA was effective from May 1, 2024 through April 30, 2025. USACE has requested reissuance with new effective dates of May 1, 2025 through April 30, 2026. The scope of the activities and anticipated effects remain the same, authorized take numbers are not changed, and the required mitigation, monitoring, and reporting remains the same as included in the initial IHA. NMFS is, therefore, issuing a second identical IHA to cover the incidental take analyzed and authorized in the initial IHA.

DATES: This authorization is effective from May 1, 2025 through April 30, 2026.

ADDRESSES: An electronic copy of the final 2023 IHA previously issued to USACE, the USACE's application, and the **Federal Register** notices proposing and issuing the initial IHA may be obtained by visiting *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Leah Davis, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA; 16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On September 7, 2023, NMFS published final notice of our issuance of an IHA authorizing take of marine mammals incidental to the Port of Nome Modification Project in Nome, Alaska (88 FR 61806). The effective dates of that IHA were May 1, 2024 through April 30, 2025. On March 4, 2024, USACE informed NMFS that the project would be delayed by one year. None of the work identified in the initial IHA (*e.g.,* pile driving and removal) has occurred. USACE subsequently submitted a request on March 18, 2024 for NMFS to reissue an identical IHA that would be effective from May 1, 2025 through April 30, 2026, in order to conduct the construction work that was analyzed and authorized through the previously issued IHA. Therefore, reissuance of the IHA is appropriate.

Summary of Specified Activity and Anticipated Impacts

The planned activities (including mitigation, monitoring, and reporting), authorized incidental take, and anticipated impacts on the affected stocks are the same as those analyzed and authorized through the previously issued IHA.

The City of Nome and USACE are proposing to expand the Port of Nome to provide much-needed additional capacity to serve the Arctic as well as to alleviate congestion at the existing port facilities. This IHA would authorize take associated with Year 1 of Phase 1 of the project only. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the initial IHA. The mitigation and monitoring are also as prescribed in the initial IHA.

Species that are expected to be taken by the planned activity include bowhead whale (*Balaena mysticetus*), minke whale (*Balaenoptera acutorostrata*), gray whale (*Eschrichtius robustus*), killer whale (*Orcinus orca*), harbor porpoise (*Phocoena phocoena*), beluga whale (*Delphinapterus leucas*), Steller sea lion (*Eumetopias jubatus*), spotted seal (*Phoca largha*), ringed seal (*Pusa hispida*), ribbon seal (*Histriophoca fasciata*), bearded seal (*Erignathus barbatus*). A description of the methods and inputs used to estimate take anticipated to occur and, ultimately, the take that was authorized is found in the previous documents referenced above. The data inputs and methods of estimating take are identical to those used in the initial IHA. NMFS has reviewed recent Stock Assessment Reports (SAR), information on relevant Unusual Mortality Events, and recent scientific literature. While the bowhead whale (Western Arctic stock) stock assessment information was updated in the draft 2023 SAR, NMFS determined that no new information affects our original analysis of impacts or take estimate under the initial IHA.

We refer to the documents related to the previously issued IHA, which include the **Federal Register** notice of the issuance of the initial 2023 IHA for the USACE's construction work (88 FR 61806, September 7, 2023), USACE's application, the **Federal Register** notice of the proposed IHA (88 FR 27464, May 2, 2023), and all associated references and documents.

Determinations

The USACE will conduct activities as analyzed in the initial 2023 IHA. As described above, the number of authorized takes of the same species and stocks of marine mammals are identical to the numbers that were found to meet the negligible impact small numbers standards and authorized under the initial IHA and no new information has emerged that would change those findings. The reissued 2024 IHA includes identical required mitigation, monitoring, and reporting measures as the initial IHA, and there is no new information suggesting that our analysis or findings should change.

Based on the information contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will

effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; and (4) USACE's activities will not have an unmitigable adverse impact on taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action with respect to environmental consequences on the human environment.

Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically excluded from further NEPA review. NMFS has determined that the application of this categorical exclusion remains appropriate for this reissued IHA.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the Alaska Regional Office, whenever we propose to authorize take for endangered or threatened species.

The effects of this proposed Federal action were adequately analyzed in NMFS' Biological Opinion for the Port of Nome Modification Project, dated July 27, 2023, which concluded that the take NMFS proposed to authorize through this IHA would not jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify any designated critical habitat.

Authorization

NMFS has issued an IHA to the USACE for in-water construction activities associated with the specified activity from May 1, 2025 through April 30, 2026. All previously described mitigation, monitoring, and reporting requirements from the initial 2021 IHA are incorporated.

Dated: April 17, 2024.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–08583 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD890]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings and Request for Comments

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

ACTION: Notice; public meetings and request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold three public hearings (one as a webinar) and accept written comments regarding an action intended to revise the species separation requirements in the Atlantic surfclam and ocean quahog fisheries.

DATES: The hearings will be held between May 9, 2024 and May 16, 2024. Written comments must be received by May 30, 2024. See **SUPPLEMENTARY INFORMATION** for details, including the dates and times for all hearings.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for hearing details.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

Written comments may be submitted to:

- *Email to: jcoakley@mafmc.org* (use subject ''SCOQ Species Separation'').
- *Via webform at: https://www.mafmc.org/comments/scoq-species-separation.*
- *Mail to:* Chris Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. Mark the outside of the envelope ''SCOQ Species Separation.''

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Council will hold three public hearings and accept written comments regarding an action intended to modify the current species separation requirements in the Atlantic surfclam and ocean quahog fisheries. Additional details, including the public hearing document can be found at: *https://www.mafmc.org/actions/scoq-species-separation.*

Hearing 1—Webinar. Thursday, May 9, 2024. 6 p.m.–9 p.m., Connection details can be found at the Council's website calendar or *https://www.mafmc.org/actions/scoq-species-separation.*

Hearing 2—Philadelphia, Pennsylvania. Tuesday May 14, 2024. 6:30 p.m.–9:30 p.m., Embassy Suites Philadelphia Airport. 9000 Bartram Avenue, Philadelphia, PA 19153; phone: (215) 365–4500.

Hearing 3—Braintree, Massachusetts. Thursday, May 16, 2024. 6:30 p.m.–9:30 p.m., Hyatt Place Boston/Braintree 50 Forbes Rd, Braintree, MA 02184; phone: (781) 848–0600.

Written comments are accepted at the hearings or via the submission methods described above, from May 1, 2024–May 30, 2024.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: April 18, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08653 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Fastener Quality Act Insignia Recordal Process

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: 0651–0028 Fastener Quality Act Insignia Recordal

Process. 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 June 24, 2024.

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.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0028 comment'' in the subject line of the message.
- *Federal eRulemaking 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 Catherine Cain, Attorney Advisor, Office of the Commissioner for Trademarks, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8946; or by email at *Catherine.Cain@uspto.gov* with ''0651–0028 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

Under section 5 of the Fastener Quality Act (FQA) of 1999,[1] 15 U.S.C. 5401 *et seq.,* certain industrial fasteners must bear an insignia identifying the manufacturer. It is also mandatory for manufacturers of fasteners covered by the FQA to submit an application to the USPTO for recordal of the insignia on the Fastener Insignia Register.

The procedures for the recordal of fastener insignia under the FQA are set forth in 15 CFR 280.300 *et seq.* The purpose of requiring both the insignia and the recordation is to ensure that certain fasteners can be traced to their manufacturers and to protect against the sale of mismarked, misrepresented, or counterfeit fasteners.

The insignia may be a unique alphanumeric designation that the USPTO will issue upon request or a trademark that is registered at the USPTO or is the subject of an application to obtain a registration. After a manufacturer submits a complete application for recordal, the USPTO issues a Certificate of Recordal. These certificates remain active for five years. Applications to renew the certificates must be filed within six months of the expiration date or, upon payment of an additional surcharge, within six months following the expiration date.

If a recorded alphanumeric designation is assigned by the manufacturer to a new owner, the designation becomes ''inactive'' and the new owner must submit an application to reactivate the designation within six months of the date of assignment. If the recordal is based on a trademark application or registration and the registration is assigned to a new owner, the recordal becomes ''inactive'' and cannot be reassigned. Instead, the new owner of the trademark application or registration must apply for a new recordal. Manufacturers who record insignia must notify the USPTO of any changes of address.

This information collection includes one form, the Application for Recordal of Insignia or Renewal/Reactivation of Recordal Under the Fastener Quality Act (PTO–1611), which provides manufacturers with a convenient way to submit a request for the recordal of a fastener insignia or to renew or reactivate an existing Certificate of Renewal.

The public uses this information collection to comply with the insignia recordal provisions of the FQA. The USPTO uses the information in this collection to record or renew insignias under the FQA and to maintain the Fastener Insignia Register, which is open for public inspection and is updated quarterly. The public may download the Fastener Insignia Register from the USPTO website.[2]

II. Method of Collection

The items in this information collection can be submitted by mail, email, or hand delivery to the USPTO.

III. Data

OMB Control Number: 0651–0028.

Forms:

- PTO–1611 (Application for Recordal of Insignia or Renewal/Reactivation of Recordal Under the Fastener Quality Act).

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 90 respondents.

Estimated Number of Annual Responses: 90 responses.

Frequency: On occasion.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 30 minutes (0.50 hours) to complete. This includes the time to gather the necessary information, prepare the form, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 45 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $20,115.

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[3] ($/hour) (f)	Estimated annual respondent cost burden (e) × (f) = (g)
1	Applications for Recordal of Insignia or Renewal/Reactivation of Recordal Under the Fastener Quality Act.	90	1	90	0.50	45	$447	$20,115
	Totals	90	.....	90	.....	45	.....	20,115

[1] *https://www.govinfo.gov/content/pkg/PLAW-106publ34/pdf/PLAW-106publ34.pdf.*

[2] *https://www.uspto.gov/trademarks/laws/fastener-quality-act-fqa/fastener-quality-act-fqa.*

[3] 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F–41. The USPTO uses the average billing rate for intellectual property work in all firms which is $447 per hour (*https://www.aipla.org/home/news-publications/economic-survey*).

Estimated Total Annual Respondent Non-hourly Cost Burden: $2,413. There are no capital start-up, maintenance 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 and postage is $2,413.

Filing Fees

The application in this information collection has two associated filing fees, resulting in $2,240 in annual non-hourly cost burden.

Item No.	Fee code	Item	Estimated annual responses (a)	Filing fee ($) (b)	Non-hourly cost burden (a) × (b) = (c)
1	6991 6992	Filing an application for recordal of insignia or renewal/reactivation of recordal.	90	$20	$1,800
1	6993 6994	Surcharge for filing six months after the expiration date—Filing an application for recordal of insignia or renewal/reactivation of recordal.	22	20	440
	Totals		112		2,240

Postage Costs

Although the USPTO prefers that the items in this information collection be submitted via email, responses may be submitted by mail through the United States Postal Service (USPS). The USPTO estimates that 17 items will be submitted in the mail. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail legal flat rate envelope, will be $10.15. Therefore, the USPTO estimates the total mailing costs for this information collection at $173.

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. The 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, the USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2024–08660 Filed 4–22–24; 8:45 am]

BILLING CODE 3510–16–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2023–0032]

Notice of Availability: Supplemental Guidance for CPSC Chronic Hazard Guidelines

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is announcing the availability of final supplemental guidance for its Chronic Hazard Guidelines. This supplemental guidance contains two guidance documents, one for the use of benchmark dose methodology in risk assessment and the other for the analysis of uncertainty and variability in risk assessment.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *www.regulations.gov* and insert the docket number, CPSC–2023–0032, in the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Eric Hooker, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2516; email: *ehooker@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1992, the Commission issued guidelines for assessing chronic hazards (Chronic Hazard Guidelines or Guidelines) under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–78, including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. 57 FR 46626. In August 2023, the Commission issued a Notice of Availability containing Proposed Supplemental Guidance for CPSC Chronic Hazard Guidelines and asked for comments on the proposed guidance. 88 FR 57947. After reviewing those comments, the Commission is now issuing the final supplemental guidance contained below in sections III and IV.[1]

Determining whether a product is or contains a hazardous substance involves scientific analysis, legal interpretation, and the application of policy judgment. The Guidelines are intended to assist firms in identifying products that present chronic hazards, to meet their labeling obligations under the FHSA and the Labeling of Hazardous Art Materials Act (LHAMA). 15 U.S.C. 1277. They are not binding on industry or the Commission. Indeed, chronic toxicity may be established in various ways. The Commission may determine that a product is a hazardous substance due to a chronic hazard based on any evidence that is relevant and material to such a determination.

[1] On April 12, 2024, the Commission voted 5–0 to approve publication of this notice. Commissioners Feldman and Dziak submitted a joint statement, available at *https://www.cpsc.gov/About-CPSC/Commissioner/Douglas-Dziak-Peter-A-Feldman/Statement/Statement-of-Commissioners-Peter-A-Feldman-and-Douglas-Dziak-on-CPSC-Chronic-Hazard-Guidelines.* Commissioner Trumka submitted a statement, available at *https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/CPSC-Revamps-Chronic-Hazards-Guidelines-Making-It-Easier-to-Protect-You-From-Toxic-Chemicals-in-Your-Home.*

For example, peer-reviewed scientific studies by third parties and toxicity assessments from CPSC's peer agencies may be relevant and material evidence to establish chronic toxicity and that a substance is a ''hazardous substance'' under the FHSA. Likewise, evidence from third parties may be useful to determine chronic toxicity. For instance, third party studies may indicate that chronic adverse health effects are associated with foreseeable levels of consumer exposure, allowing the Commission to conclude that the FHSA's criteria for a ''hazardous substance'' are satisfied. Other cases, however, may require original research to fill gaps in knowledge.

In addition, while the Guidelines describe certain toxic endpoints, they do not limit the toxic endpoints the Commission may consider. The Commission may consider all forms of personal injury or illness as potential toxic endpoints.

The Chronic Hazard Guidelines, which should be understood as a set of best practices, are not mandatory for the Commission or for stakeholders. The guidelines describe methods that CPSC staff may use to assess chronic hazards under the FHSA. Furthermore, the guidelines are intended to be sufficiently flexible to incorporate the latest scientific information, such as advances in risk assessment methodology. Risk assessors may deviate from the default assumptions described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data as indicated in section VI.A.2 of the preamble of the guidelines. 57 FR 46633. However, given that the guidelines represent an available set of best practices, risk assessors are encouraged to use the information and approaches outlined therein where appropriate.

In the years since the guidelines were issued, there have been numerous advances in the basic science underlying the guidelines, such as the use of transgenic animals to elucidate mechanisms of carcinogenicity and toxicity. There also have been several changes in the practice of risk assessment, including wider acceptance and use of risk assessment methods such as the benchmark dose approach and probabilistic exposure assessment. Therefore, CPSC is finalizing two guidance documents to supplement the 1992 guidelines.

The first supplement provides guidance for the application of benchmark dose methodology (BMD) to risk assessment. This supplement discusses an alternative to the traditional approach described in the original guidelines for estimating acceptable daily intakes (ADIs) for carcinogenic and other hazards, such as neurotoxicological or reproductive/developmental hazards. The second supplement is guidance for the analysis of uncertainty and variability, including use of probabilistic risk assessment methodology, which is most relevant to exposure assessment.

Like the 1992 guidelines, the supplemental guidance documents are not mandatory. Rather, they describe methods that CPSC staff and manufacturers may use to evaluate chronic hazards. The guidelines are intended to assist manufacturers in complying with the requirements of the FHSA and to facilitate the use of reliable risk assessment methodologies by both manufacturers and CPSC staff.

II. Response to Comments

In response to the Commission's August 2023 Notice of Availability of the proposed supplemental guidance, the Commission received two comments. The commenters were the National Center for Health Research (NCHR) and one individual, Albert Donnay. They had questions about the timing of the release of the guidance, technical details of benchmark dose modeling, how to determine risk assessment approaches in the context of the guidance, and the citation of references after the 2008 peer review of the supplemental guidance.

Comment 1: NCHR noted that time has passed since a draft of the Supplemental Guidance was peer reviewed in 2008.

Response 1: Although the Supplemental Guidance might have been finalized earlier, the methods and approaches described in the Chronic Hazard Guidelines and the Supplemental Guidance are neither mandatory nor proscriptive. Publication of the Supplemental Guidance does not change the Commission's substantive policies. As before, risk assessors are encouraged to use modern and applicable approaches to identify and quantify consumer product chemical hazards and risks, provided that methods and assumptions are documented, scientifically defensible, and supported by appropriate data.

Comment 2: NCHR questioned whether it is appropriate to recommend using linear modeling of benchmark dose assessment for all carcinogens and non-carcinogens.

Response 2: Linear dose-response modeling describes a constant proportional increase in a biological response (*e.g.,* toxicity) as the dose or exposure level increases and is often used for low dose cancer risk assessments. Contrary to this comment, the supplemental guidance does not recommend linear modeling for *all* carcinogens and noncarcinogens. For non-cancer endpoints, the supplemental guidance specifically states that ''a non-linear dose response is generally presumed. . . .'' On the other hand, for cancer risk, the Commission prefers linear extrapolation to the background level from the BMD as a point of departure (PoD). However, the guidance also describes that a non-linear dose response with use of uncertainty factors may be used if there is convincing evidence that the dose response is non-linear at low doses. The preference for the linear assumption is based on theoretical considerations of carcinogenicity, as well as modeling considerations, which are described in detail in the Chronic Hazard Guidelines and the Supplemental Guidance. The supplemental guidance also states that risk assessors may use methods other than those described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data.

Comment 3: NCHR requested more specific guidance as to the conditions under which it would be acceptable to deviate from the assessment methodology outlined in the guidance.

Response 3: CPSC's reference to the use of professional judgment is based on its expectation that the risk assessor has the training, expertise, and experience to analyze datasets using the tools and approaches that are most appropriate and relevant to meet the needs and requirements for each assessment. The Commission understands that a variety of tools, models, and methods currently exist, and anticipates further advancements in this science. Thus, the supplemental guidance reiterates that expertise and professional judgment are required when applying the guidelines and emphasizes that the guidelines cannot be applied mechanically.

Comment 4: Albert Donnay asked when these supplements were most recently revised, what contractor(s) contributed to the latest revisions if they were not done solely by staff, and how many independent scientists with expertise in either BMD or PRA reviewed the post-2008 revisions before they were published in the FR.

Response 4: After the peer review of the supplements conducted in 2008, CPSC staff revised and updated the proposed supplements to incorporate discussion of more recently released

tools, such as benchmark dose software packages and supporting guidance documents from the U.S. Environmental Protection Agency (EPA) and the Dutch National Institute for Public Health and the Environment (RIVM). In addition, CPSC staff updated the references in the draft supplemental guidance to include literature published after 2008 and assessed that the more recent literature did not indicate a need for revision of the draft supplemental guidance or for additional independent review. These updates were performed by CPSC staff without participation of contractors.

Having considered the comments, the Commission is finalizing the guidance as proposed, without changes. The Final Supplemental Guidance for the Use of Benchmark Dose Methodology in Risk Assessment and Final Supplemental Guidance for the Analysis of Uncertainty and Variability in Risk Assessment are stated in sections III and IV.

III. Final Supplemental Guidance for the Use of Benchmark Dose Methodology in Risk Assessment

A. Background

In 1992, the U.S. Consumer Product Safety Commission (CPSC) issued guidelines for assessing chronic hazards under the Federal Hazardous Substances Act (FHSA) and the Labeling of Hazardous Art Materials Act (LHAMA), including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk (CPSC 1992). 57 FR 46626. The chronic hazard guidelines, which are not mandatory for CPSC or stakeholders, are intended as an aid to manufacturers in making their determination of whether a product is a hazardous substance due to chronic toxicity, and thus would require labeling under the FHSA. The guidelines describe methods that CPSC staff use to assess chronic hazards under the FHSA. Furthermore, the guidelines are intended to be sufficiently flexible to incorporate the latest scientific information, such as advances in risk assessment methodology. Risk assessors may deviate from the default assumptions described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data. However, given that the guidelines represent an available set of best practices, risk assessors are encouraged to use the information and approaches outlined therein where appropriate, and other methods will be reviewed by staff to determine acceptability.

In the years since the guidelines were issued, there have been numerous advances in the basic science underlying the guidelines, such as the use of alternative methods to elucidate mechanisms of carcinogenicity and toxicity. There also have been several changes in the practice of risk assessment, such as in the assessment of risks to children, as well as wider acceptance and use of risk assessment methods such as the benchmark dose approach and probabilistic exposure assessment. Therefore, CPSC staff-initiated reviews of the existing chronic hazard guidelines and is recommending additions or changes, as appropriate. The purpose of this document is to describe supplemental guidance for the application of the benchmark dose approach in risk assessment.

The current scientific knowledge regarding the risk assessment of chronic hazards is such that the guidelines cannot be applied mechanically (CPSC 1992, section VI.A.2, page 46633). Rather, considerable expertise and professional judgment are required to apply the guidelines properly. Furthermore, the volume of scientific literature on chronic hazard risk assessment, in general, and the benchmark dose, in particular, is extensive. Therefore, the discussion and guidance described below are not intended to explain how to perform chronic hazard risk assessments using the methods described. The guidelines assume that the reader has the necessary expertise. In addition, the discussion presented here is necessarily brief. The risk assessor is referred to the literature on benchmark dose, only a portion of which is cited here.

B. Discussion

The benchmark dose (BMD) approach (Crump 1984a; Crump et al. 1995) is an alternative to the traditional method of deriving acceptable daily intake (ADI) [2] levels by using no observed adverse effect levels (NOAELs) [3] and lowest observed adverse effect levels (LOAELs). The BMD may be used for both cancer and non-cancer endpoints, quantal or continuous data, and animal or human data. The BMD is an estimate of the dose level for a particular response. For example, the BMD_{10} is the best estimate of the dose at an excess risk (risk over background) of 10%, and the $BMDL_{10}$ is the lower confidence limit (LCL) of the BMD_{10}. The benchmark response (BMR) level is the response level selected for deriving an ADI level or cancer unit risk (slope factor).[4] The BMR is within or near the observable range of the bioassay used to derive the ADI or unit risk. Typically, selected BMR's range from 1% to 10% excess risk. To derive an ADI for non-cancer endpoints, the BMD is divided by the same uncertainty (safety) factors that are normally applied to the NOAEL. For cancer risk, the BMD is used as a ''point of departure'' (PoD) for linear extrapolation to the background level (EPA 2005). However, uncertainty factors may be applied for cancer risk if there is convincing evidence for a non-linear dose response at low doses.

1. Advantages of the BMD Approach

The advantages of the BMD approach have been described in detail elsewhere (Barnes et al. 1995; Crump 1984a; Crump et al. 1995; Gaylor et al. 1998; EPA, 2012; Filipsson et al. 2003). For example, the NOAEL and LOAEL are limited to the doses tested in the bioassay. In contrast, the BMD is not limited to the doses tested in the bioassay. Thus, the BMD provides a more consistent basis for comparisons between studies that did not use the same dose levels.

The true (parametric) value of the BMD is independent of the study design, such as the number of animals per dose group, *n.* However, the NOAEL is sensitive to *n.* The NOAEL is not a threshold, although it is frequently regarded as such. Rather, it is more appropriate to regard the NOAEL as a limit of detection. The incidence of adverse effects may be as high as 20% at the NOAEL. A given dose level may be a NOAEL in a study with small *n* if the incidence is not significantly different from background. However, the same dose in a larger study may be a LOAEL due to the increased sensitivity resulting from a larger *n.* The traditional NOAEL approach ''rewards'' studies with small *n,* by resulting in higher (*i.e.,* less protective) NOAELs. Conversely, the traditional approach ''penalizes'' studies with larger *n,* by resulting in lower (more protective) NOAELs. Thus, the traditional method is a disincentive to performing better, larger studies. In contrast, the BMD is essentially independent of *n* and,

[2] The ADI is an estimate of the amount of a chemical a person can be exposed to on a daily basis over an extended period of time (up to a lifetime) with a negligible risk of suffering deleterious effects. The ADI is roughly equivalent to a ''reference dose'' or ''tolerable daily intake.''

[3] In the chronic hazard guidelines, ''NOEL'' is used synonymously with ''NOAEL,'' because only adverse effects are relevant under the FHSA.

[4] The term ''unit risk'' is used synonymously with ''slope factor'' (CPSC 1992).

therefore, does not penalize studies with a larger *n*.

The BMD approach may account for variability in the bioassay. If the BMDL is used, larger studies tend to have smaller confidence intervals. Thus, larger studies are generally rewarded, because a smaller confidence interval leads to a higher BMDL. In contrast, poorly designed studies with inadequate sample size are penalized by having larger confidence intervals, leading to a lower BMDL.

The BMD accounts for the slope and shape of the dose response curve and uses all of the dose response data from the study. In contrast, the NOAEL or LOAEL relies on the response at only one dose level. Thus, information on the slope and shape of the dose response curve is ignored.

With the BMD approach, the methodology is the same regardless of whether a NOAEL is established. An additional uncertainty factor that is generally applied when using the LOAEL is not required in a BMD analysis, because the BMD can still be estimated even if a NOAEL has not been established.

While there are several advantages to the BMD approach, the principal disadvantage is the added complexity of the methodology. BMD methods require expertise in statistics, as well as toxicology. The additional steps involved in the analysis also increases the number of decision points, such as the choice of BMD and mathematical model, which require professional judgment. This, in turn, increases the number and possibly the range of possible ADI values from a given data set and may lead to areas of disagreement among risk assessors.

2. BMD Methodology

While the overall BMD approach is straightforward, there are many factors that must be considered in applying BMD methods in risk assessment, including the selection of the most appropriate endpoint and data set, dose response model, statistical methods, and selection of the BMD. Each of these factors requires knowledge of toxicology and risk assessment, as well as professional judgment.

a. Selection of the Endpoint and Data Set to Model

Initially, the selection of the critical study and endpoint to model is similar to the traditional approach. The study should be well-designed and executed, with an adequate number of animals and doses, and a statistically significant effect (CPSC 1992, sections VI.C.3.a, p. 46639; VIC.3.b, p. 46640; VI.D.2.a, p. 46642; and VI.D.3.b, p. 46643). There should be a dose where there are no observed adverse effects, *i.e.,* at or near the NOAEL. The selection of the critical endpoint is based, in part, on the judgment of the toxicologist or pathologist regarding the biological significance of the endpoint. When multiple studies, multiple endpoints, or multiple species are available, generally the most sensitive dose response is used (CPSC 1992, section F.4.b.ii, p. 46656).

It should be noted that the study with the lowest NOAEL will not necessarily lead to the lowest BMD, because the BMD also depends on the slope of the dose-response curve. Therefore, all relevant endpoints and studies should be modeled (Filipsson et al. 2005) to ensure that the lowest BMD is identified.

Additionally, the data set must be amenable to modeling. That is, there should be a steadily increasing dose response that is not saturated at the high doses. If none of the available dose response models can adequately fit the data (see below), the BMD approach cannot be used.

b. Selection of the Dose Response Model

The BMD approach is essentially a curve-fitting exercise. The choice of the dose-response model does not require any knowledge of the mode of action. Thus, the form of the model is not necessarily prescribed or dictated by any specific information about the studied activity, provided that it adequately describes the data. In some instances, however, mechanistic information may suggest a particular model, such as the Hill model when cooperative binding is observed.

A variety of dose-response models have been used to estimate the BMD (Crump 1984a; Crump et al. 1995; EPA 2022; Filipsson et al. 2003; Gaylor et al. 1998). The BMD approach may be applied to either quantal (dichotomous) or continuous data. Incidence data, such as the number of animals with a certain adverse effect, are quantal. Serum enzyme or hormone levels are examples of continuous data. Generally, quantal and continuous data require different, though related, dose response models. Nested quantal models may be used with developmental studies to evaluate effects within and between litters.

Dose response models for quantal data include linear (one-hit), quadratic, gamma multi-hit, Weibull, polynomial (multistage), logistic, log-logistic, probit, and log-probit models. These are slightly modified versions of the dose response models that have been used for cancer risk assessment (compare Crump 1984b; Zeise et al. 1987). The linear, quadratic, and Weibull models are essentially subsets of the polynomial model. Therefore, some or all of these models may yield similar results for certain data sets, such as when the dose response is linear. Dose response models for continuous data include linear, quadratic, linear-quadratic, polynomial, power, and Hill models. In addition, nested models are available for developmental studies. The mathematical forms of the models are described in detail elsewhere (Crump 1984a; Crump et al. 1995; EPA 2022; Filipsson et al. 2003; Gaylor et al. 1998).

In applying the BMD approach to non-cancer endpoints, the dose response models are not used for low-dose extrapolation. Thus, in contrast to cancer risk assessment, there is no need to consider the shape of the curve at low doses. Therefore, the choice of dose response model depends, in large part, on the goodness of fit. That is, the model (or models) selected must adequately describe the data. A model is generally rejected if the probability based on chi-square is less than 0.05. In other words, if the probability that the deviation of the data from the model is due to random variability is less than 0.05, the model does not adequately describe the data. Depending on the data set, multiple models may provide a similar global fit to the data. In this case, the local fit in the low-dose range, that is, the doses nearest the BMR, may be considered. In practice, different models often result in roughly similar BMDs, provided that they adequately describe the data. In any case, the results from different models and the choice of model should be discussed.

In some cases, it may be necessary to exclude high dose data from the model fitting procedure, to improve the goodness of fit. Data at the highest doses of a multiple dose bioassay may be considered to be less informative for the purpose of low dose extrapolation, especially in cases where the responses plateau at the high doses. Therefore, high dose groups may be systematically eliminated until the fit is acceptable (Anderson 1983).

In other cases, such as when a non-monotonic dose response is observed, none of the dose response models may be able to fit the data adequately. When this occurs, the BMD approach should not be used. While the NOAEL/LOAEL approach could still be applied, the quality of the study should be given careful consideration. It may not be appropriate to derive an ADI by any method from such a data set.

The steps for estimating the BMD may be summarized as follows:

- Select the bioassay(s) and endpoint(s) to model.
- Determine whether the data are quantal or continuous.
- Fit the bioassay data set(s) to several dose response models and determine the goodness of fit. Calculate multiple BMDs, including maximum likelihood estimates (MLEs) of risk and confidence limits. Graph the results.
- Select which model to use for determining the ADI. Generally, the model giving the best fit is used. If multiple models fit the data well, the local fit near the BMR may be considered. In some cases, the choice of model may be based on mechanistic considerations. If no model fits the data adequately, the BMD approach should not be used.
- If multiple endpoints or bioassays are modeled, select which to use for determining the ADI. The most sensitive dose response is generally used (CPSC 1992, section F.4.b.ii, page 46656). Other factors, such as severity of the effect may also be considered.
- Select which BMD (BMR) to use for deriving the ADI.
- Discuss and explain all of the decision points in the preceding steps.

c. Statistical Methods

Various types of software may be used to estimate the BMD/BMDL. The U.S. Environmental Protection Agency (EPA) has developed Benchmark Dose Software (BMDS) specifically for this purpose (EPA 2022). The BMDS and associated documentation are in the public domain and may be downloaded from the EPA website. Software is also available from the Netherlands Ministry of the Environment (RIVM 2021) and Shao and Shapiro (2018). Various other statistical software packages (*e.g.,* SAS, and R) may also be used. Likelihood methods are generally preferred for estimating the BMD and confidence limits (Crump 1984a; Crump and Howe 1985; Crump et al. 1995; Gaylor et al. 1998; EPA 2001). Goodness of fit is typically based on the chi-square distribution.

As with cancer risk assessment, CPSC staff prefers to use extra risk, rather than additional risk, as a measure of the risk over background. Extra risk applies Abbott's correction, so that animals which already have a given lesion from background processes are not considered at risk for an exposure-induced lesion of the same type. The numerical difference between extra risk and additional risk is small, provided that the background risk is sufficiently low (<0.25). Extra risk (Crump and Howe 1985) is defined by:

$$P_E = \frac{P_D - P_0}{1 - P_0}$$

where:

P_E is the extra risk, P_D is the risk at dose D, and P_0 is the background dose.

Additional risk is defined by:

$$P_A = P_D - P_0 \qquad (2)$$

where:

P_A is the additional risk.

d. Selection of the Benchmark Dose (BMD)—Quantal Data

The ADI is the dose at which the risk of an adverse effect is considered negligible. Because such risks cannot be directly measured, this requires assumptions about the shape of the dose response curve in the low dose region. For cancer, there are theoretical reasons for assuming a linear response at low dose, such as the probability that a given chemical will interact with background processes or other chemicals (CPSC 1992, VI.F.3.b.ii, page 46654). For non-cancer endpoints, a non-linear dose response is generally presumed, although the shape and slope of this curve outside of the observable range is unknown.

The selection of the BMD has been based on the following considerations: (i) The BMD should be within or near the observable range of the bioassay. (ii) It is roughly the dose at which a statistically significant effect may be observed in the bioassay (Crump et al. 1995). Thus, BMD's of 5% to 10% over background are typically used for quantal data, assuming that there is an adequate number of animals and the background level is not exceptionally high. (iii) The BMD approach is an alternative to deriving the ADI from a NOAEL. The BMD has generally been selected to approximate the NOAEL (Crump et al. 1995). Thus, the study selected for estimating the BMD should include a dose at or near the NOAEL. Other factors, such as the shape of the dose response curve or the study design (*e.g.,* CPSC 2001, 2002), may be considered on a case-by-case basis. For example, it may be desirable to select a BMD that is reflective of nonlinearity or an inflection point in the dose response curve (Murrell et al. 1998).

It is important to keep in mind that the selection of a BMD is part of the overall risk assessment process, which includes the selection of the critical endpoint and uncertainty factors, among other things. The overall process is equally as important as the individual steps. For example, the risk assessor might consider applying different uncertainty factors, depending on the BMD selected. That is, consideration could be given to larger or additional uncertainty factors if the BMD is higher than is typical, or to smaller uncertainty factors if the BMD is exceptionally low.

Numerous authors (Barnes et al. 1995; Crump 1984a; Filipsson et al. 2003) and the EPA (EPA 2005) generally recommend using the 95% lower confidence limit (LCL) of the benchmark, typically the $BMDL_{05}$ or $BMDL_{10}$. This generally satisfies the criteria listed above. In a typical bioassay, the LCL is within or near the observable range, it is near the lowest detectable response, and it is roughly equivalent to the NOAEL. Using the LCL takes into account the uncertainty in the bioassay and tends to reward larger or better studies, which generally have narrower confidence intervals. On the other hand, it has been argued that using the LCL rather than the best estimate (maximum likelihood estimate or MLE) leads to a BMD that may depend more on experimental uncertainty than on the dose response itself (Murrell et al. 1998). Thus, using the LCL tends to defeat one of the principal advantages of the BMD approach, which is to make use of the

shape and slope of the dose-response curve in the analysis.

While the choice of the BMD should be made on a case-by-case basis, it is desirable to have a default value for the purpose of consistency across different chemicals, endpoints, and risk assessors. However, even if the default value is used, the risk assessor must evaluate whether the default is appropriate in a given case, using the criteria described above. Risk assessors have most frequently used $BMDL_{05}$ or $BMDL_{10}$ to derive ADIs (or RfDs) (see above). The Chronic Hazard Advisory Panel (CHAP) convened by CPSC (CPSC 2001) and CPSC staff (CPSC 2002) used the BMD_{05} to set an ADI level for diisononyl phthalate. Health Canada also uses the BMD_{05} to set tolerable intake levels. One advantage of using the MLE is that it is more reflective of the shape of the dose response than the LCL (Murrell et al. 1998).

For cancer risk assessment, CPSC prefers to use the MLE risk (see below). However, as currently applied, the ADI is not regarded as a numerical estimate of risk, as is the case for cancer risk. Rather, it is regarded as a regulatory threshold, that is, a ''negligible risk level'' or ''virtually safe dose.'' Therefore, the reasons for using the MLE to estimate cancer risk do not necessarily apply to ADIs. This conclusion may change in the future, if true risk-based approaches are applied to non-cancer endpoints.

At the present time it seems reasonable to use the BMD_{05} (*i.e.,* the MLE) rather than the $BMDL_{05}$ (*i.e.,* the LCL) as a default value, subject to the limitations discussed above. This is consistent with the CPSC approach to estimating cancer risk and with previous CPSC applications of the BMD approach. In addition, the MLE better reflects the shape of the dose response, as compared to the LCL.

e. Selection of the Benchmark Dose (BMD)—Continuous Data

For continuous data, the BMD value is generally a level that is considered ''adverse.'' This is a matter of professional judgment by health scientists, such as toxicologists and pathologists, and must be determined on a case-by-case basis. As discussed in the previous section on ''Selection of the Benchmark Dose (BMD)—Quantal Data,'', the MLE value is preferred for risk assessment. In instances where there is no consensus on what constitutes an adverse effect, some risk assessors have used a relative change in the endpoint, such as a change of one standard deviation.

3. Cancer Risk Assessment

The multistage model (Crump 1984b) has been preferred by most federal agencies for cancer risk assessment. The multistage model is defined by:

$$P_D = 1 - e^{-[q_0 + q_1 D + q_2 D^2 \ldots q_9 D^9]} \quad (3)$$

where:

D, dose; P_D, cancer risk at dose D; and $q_0 \ldots q_9$, parameters to be fitted by the model.

The EPA has preferred to use the upper confidence limit (UCL) of the estimated risk, while CPSC staff uses the MLE risk, unless the linear term (q_1) is zero. When q_1 is zero, the UCL risk is used to ensure linearity at low doses (CPSC 1992, VI.F.3.b.ii, page 46654).

EPA began to use the BMD approach for cancer risk assessment in place of the multistage model in 2005 (EPA 2005). BMD is the preferred method for dose response assessment at EPA and other agencies (Allen et al. 2011). The default procedure is to use the BMR as a point of departure (PoD) for linear extrapolation to the background level. Uncertainty factors may be applied if there is sufficient reason to rule out a linear dose response at low doses. This procedure is analogous to the Mantel-Bryan procedure (Mantel & Bryan 1961; see also Gaylor & Kodell 1980) that was commonly used before the multistage model became available.

The BMD approach described by EPA is consistent with the default procedures used by CPSC staff under the guidelines. The primary concern of CPSC staff is that linear extrapolation should remain the default procedure for guidelines purposes. The results from using the BMD methodology and the multistage model are not substantially different when linear extrapolation is assumed. In general, a non-linear dose response with use of uncertainty factors should be used only if there is convincing evidence that the dose response is non-linear at low doses. In addition, the BMD approach offers certain advantages over the multistage model as applied by CPSC staff. While staff prefers to use the MLE estimate of cancer risk, it is necessary to use the UCL risk in cases where the linear term (q_1) is zero. By using the BMD approach, the MLE risk can be used in all cases. Thus, the process is simplified. In addition, staff use the BMD approach for non-cancer endpoints, BMD methods are used by EPA and other agencies for both cancer and non-cancer risk assessment, and the software is widely available.

The practice of the CPSC Directorate for Health Sciences (HS) is to present the best estimate of risk, rather than the upper bound, to risk managers. Thus, HS prefers the MLE of risk in cancer risk assessments (CPSC 1992, section VI.F.3.b.iii). Presenting the best estimate of risk depends on a number of considerations: (i) CPSC does not routinely define ''safe'' levels, as is frequently done by other agencies such as the Food and Drug Administration (FDA) and EPA. Rather, the need for CPSC actions based on unsafe levels are typically determined on a case-by-case basis. (ii) For typical cancer bioassays in animals, the difference between the MLE and 95% upper confidence limit (UCL) [5] is generally small, about 2- to 3-fold. (iii) The overall risk assessment process is designed to include assumptions that tend to err on the side of safety when data are lacking for a particular part of the assessment. Thus, there is always a possibility of compounding safety assumptions which could result in some cases in unrealistic estimates. Therefore, the use of the MLE rather than the UCL generally has a small effect on numerical estimates.

Therefore, the BMD approach with linear extrapolation and based on the MLE risk generally will be the default procedure for cancer risk assessments performed by CPSC staff. To further simplify the process, the multistage (polynomial) model generally will be the default model for cancer risk. However, other models that adequately describe the data may be used, as described above for non-cancer endpoints. While the choice of a PoD is not critical, the default will be the BMD_{05} (see above). Although the BMD approach will be the default procedure, the multistage model, as described above, can still be used. Risk assessors may deviate from the default assumptions described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data (CPSC 1992, section VI.A.2).

[5] The UCL risk corresponds to the LCL dose.

The following practices are recommended when applying benchmark dose methodology:

- The BMD approach is generally the preferred method for setting ADI levels for non-cancer endpoints, provided that adequate dose response data are available.
- Appropriate dose response models and statistical methods have been described in detail elsewhere (Crump 1984a; Crump et al. 1995). Public domain software is available from EPA (EPA 2022).
- The BMD response level (BMR) used to calculate the ADI will be determined on a case-by-case basis. A range of BMR's, including best estimates and lower confidence limits, should be considered.
- As a default, CPSC staff will use the maximum likelihood estimate of the dose at which the extra risk is 5% (BMD_{05}). The same uncertainty factors currently applied to the NOAEL will be applied to the BMD.
- Several dose response models should be considered. Generally, the model that best describes the observed dose response data will be selected to derive the ADI. In addition, the ADI will generally be based on the combination of dose response model, endpoint, and study that lead to the lowest ADI.
- Risk assessors may deviate from the default assumptions described in the guidelines, provided that their methods and assumptions are documented, scientifically defensible, and supported by appropriate data (CPSC 1992, section VI.A.2). While the BMD approach is typically preferred, the traditional method based on NOAELs/LOAELs may still be used.

In addition, the BMD approach with linear extrapolation and based on the MLE risk will be the default procedure for cancer risk assessments performed by CPSC staff. The multistage (polynomial) model will be the default model for cancer risk. However, other models that adequately describe the data may be used, as described above for non-cancer endpoints. While the choice of a PoD is not critical, the default will be the BMD_{05}. Linear extrapolation from the PoD generally will be used unless there is convincing evidence that the dose response will be non-linear at low doses (CPSC 1992, VI.F.3.b.ii, page 46654). In cases where a non-linear dose response is justified, uncertainty factors may be applied as described for non-cancer endpoints. Although the BMD approach will be the preferred procedure, the multistage model, as traditionally applied by CPSC, can still be used.

C. Summary

1. Estimation of the Acceptable Daily Intake for Non-Cancer Endpoints

The following supplements the guidance on estimating acceptable daily intakes (ADIs) in the CPSC Chronic Hazard Guidelines at 57 FR 46656 (Oct. 9, 1992) in section VI.F.4.b.1.ii. This does not supersede the 1992 guidance; rather, it provides guidance on the use of newer methods for estimating ADIs.

Traditionally, CPSC staff derived acceptable daily intake (ADI) levels for non-cancer endpoints by applying safety factors (uncertainty factors) to the no-observed-effect level (NOAEL) or lowest-observed-effect-level (LOAEL). However, the benchmark dose (BMD) approach is now generally preferred over the traditional method. The benchmark dose is an estimate of the dose at a certain risk level. The BMD is estimated from a dose-response model. The advantages of the BMD approach and methods for estimating the BMD are described elsewhere (Barnes et al. 1995; Crump 1984; Crump et al. 1995; EPA 2012; Filipsson et al. 2003; Gaylor et al. 1998). Software for estimating the BMD is available from the U.S. EPA (EPA 2022) and other sources. In estimating the BMD, the risk assessor should consider the following points: (a) The dose-response model must provide an adequate fit to the data; the BMD approach may not be appropriate for all data sets. (b) Alternative dose response models should be considered, and the choice of model to derive the ADI explained. (c) Alternative endpoints and studies should also be considered, as appropriate. (d) A range of BMD response levels, including best estimates and confidence intervals should be evaluated. (e) Generally, different methods are required for dichotomous and continuous data.

The BMD selected to derive the ADI (BMD response level) is determined on a case-by-case basis. The BMD response level (BMR) must be within or near the range of experimental dose levels. As a default, for dichotomous (*i.e.,* incidence) data, the BMR will be the maximum likelihood estimate of the dose associated with an extra risk (risk over background) of 5% (BMD_{05}). For continuous data, (*e.g.,* enzyme or hormone levels), the BMD is generally based on the level considered to be an adverse effect. The default safety (uncertainty) factors described above (10-fold for human data and 100-fold for animal data) are applied to the BMD CPSC 1992, section VI.F.4.b.1.ii; Haber et al. 2018). Thus, the ADI is generally 100-fold lower than a BMD based on animal data. An additional uncertainty factor for ADIs based on a LOEL is not needed. While the BMD approach is preferred, the traditional method of applying safety factors to the NOAEL or LOAEL may still be used.

2. Estimation of Cancer Risk

The following is a supplement to the CPSC Chronic Hazard Guidelines at 57 FR 46654 (Oct. 9, 1992), section VI.F.3.b.ii.

Traditionally, CPSC staff estimated cancer unit risks (slope factors) using the multistage model (Global83). The maximum likelihood estimate (MLE) of risk was used unless the linear term (q_1) was equal to zero; in this case, the upper confidence limit of risk was used. However, the benchmark dose (BMD) approach with linear extrapolation based on the MLE risk is now generally preferred over the traditional method. The multistage (polynomial) model will be the default model for cancer risk. However, other models that adequately describe the data may be used, as described above for non-cancer endpoints. The choice of a BMD response level (BMR) or point-of-departure (PoD) will be made on a case-by-case basis. In general, the default PoD will be the MLE estimate of the dose associated with an extra risk (risk over background) of 5% (BMD_{05}). Linear extrapolation from the PoD will be used unless there is convincing evidence that the dose response will be non-linear at low doses. In cases where a non-linear dose response is justified, uncertainty factors may be applied as described for non-cancer endpoints. Although the BMD approach generally is preferred under the guidelines, the traditional CPSC approach based on the multistage model may still be used.

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IV. Final Supplemental Guidance for the Analysis of Uncertainty and Variability in Risk Assessment

A. Background

In 1992, the U.S. Consumer Product Safety Commission (CPSC) issued guidelines for assessing chronic hazards under the Federal Hazardous Substances Act (FHSA), including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. The guidelines are detailed in a **Federal Register** notice. 57 FR 46626 (Oct. 9, 1992).

The chronic hazard guidelines are intended as an aid to manufacturers in making their determination of whether a product is a hazardous substance due to chronic toxicity, and thus would require labeling under the FHSA. The guidelines are not mandatory. The guidelines describe standard methods CPSC staff may use to assess chronic hazards under the FHSA. The guidelines are intended to be sufficiently flexible to incorporate the latest scientific information, such as advances in risk assessment methodology. Therefore, CPSC staff initiated reviews of the existing guidelines and is recommending additions or changes, as appropriate. The purpose of this document is to describe supplemental guidance for the analysis of uncertainty and variability in risk assessment, including the use of probabilistic techniques.

B. Discussion

In toxicological risk assessment, uncertainty is the term used to describe the lack of knowledge in the underlying science, such as when few measurements of the particular subject have been made. Uncertainty may also be associated with the choice of mathematical model used to estimate exposure or risk. Variability refers to inherent differences due to heterogeneity or diversity in the population or exposure variable, such as body weight of people in the exposed population. Variability is generally not reducible by improved measurement or further study (EPA 1997, 2014).

The theory and techniques of exposure assessment have been discussed in detail elsewhere (CPSC 1992; EPA 2014, 2019; Paustenbach 2002). Exposure may be measured directly, but, in general, an exposure assessment is often based on a mathematical model that combines several variables describing the factors that influence exposure. For example, an assessment of exposure to a chemical released into the air during use of a product will include information about the emission rate into the air, the resulting concentration of the chemical in the air, the amount of time a person using the product or spent living, working, or playing in the area, and the amount of air a person breathes during the exposure. For a given exposure scenario, the output of an exposure assessment is typically an estimate of the amount of chemical that comes into contact with the body, usually expressed per unit of body weight per day during a defined period of time or over a lifetime, although exposure may be defined in other terms.

For carcinogens, ''risk'' is the product of the exposure estimate and the dose-response value, *i.e.,* the numerical representation of cancer risk per unit of daily exposure. For non-carcinogens, the exposure estimate is compared with the ''acceptable daily intake'' (ADI), which is the level of exposure at which we expect humans not to experience harmful health effects. Although there is no numerical estimate of ''risk'' in this latter case, one may calculate the hazard index (HI), which is the ratio of the estimated exposure to the ADI (HI greater than one means that the exposure may be hazardous; HI less than one represents negligible risk).

There is no single, correct way to conduct an exposure or risk assessment for purposes of evaluating chronic hazards under the Federal Hazardous Substances Act (FHSA) or the Labeling of Hazardous Art Materials Act

(LHAMA). There are, however, important issues and concerns that are commonly encountered in risk assessment that should be considered regardless of the specific risk assessment approach. Because risk assessment is a rapidly advancing field, the discussions here should be supplemented with other information from the scientific literature, texts, and government agency guidance, as scientifically appropriate.

In most cases, the risk assessor will consider uncertainty and variability in the assessment and, at a minimum, include a discussion of the effect of uncertainty and variability on the final risk estimates. The discussion may be qualitative or it may include quantitative estimates of uncertainty and variability. Variability and uncertainty are distinct issues and should be considered separately in each analysis using appropriate statistical techniques, such as two-dimensional probabilistic analyses (Cullen and Frey 1999). In practice, however, increasingly complex analyses may not be warranted for every situation, as discussed below. In addition, the available data may not be sufficient to distinguish between variability and uncertainty or to allow statistical consideration of both issues.

Risk assessors may take one of two general approaches to conduct risk assessments: deterministic or probabilistic (stochastic) modeling. Of these, probabilistic techniques explicitly include quantification of uncertainty and variability.

Risk analyses have long been grounded on deterministic approaches. Probabilistic risk assessments have been used for many years in predicting accidents and systems failures, and in weather forecasting. Over time, probabilistic approaches have been applied to ecological and human health risk assessments (Kendall et al., 2001).

Deterministic and probabilistic modeling are both valid mathematical approaches for estimating risk. The key difference between these approaches is that deterministic modeling enters point estimates (*i.e.,* single values) for the model's inputs while probabilistic modeling uses probability distributions for some or all inputs in conjunction with statistical techniques such as Monte Carlo analysis. Consequently, the output of a deterministic assessment is a point estimate of the exposure or risk for the exposed individual or population. A probabilistic approach results in a distribution of exposure or risk estimates, which may provide additional information about the variability in the exposure of interest and the uncertainty in the analysis or of the true, but unknown risk.

Exposure and risk assessments are conducted for many different reasons, such as to answer specific questions about exposure scenarios, inform decision-making, and explore options. The ultimate application of the assessment will help determine the methodological approaches and techniques to be used. The choice of approach may be based on considerations of the available scientific information, institutional policies, time and resources available, or social implications.

Risk assessments may be iterative, *e.g.,* subject to collection of new data or refinement of existing data. Assessments may be conducted in a tiered approach, in which each analysis is based on the knowledge and resources available to the risk assessor and the needs of decision-makers and stakeholders. In general, risk analysts will work from the simple to the complex until, for example, the problem has been sufficiently characterized so that risk managers may proceed with decision-making and initiate any actions required to manage the hazard. An initial analysis may be conducted to determine whether a given exposure scenario is associated with relatively high or relatively low risk. For example, protective assumptions are sometimes used initially to characterize the level of risk. If such an assessment indicates a relatively high risk, the analyst may choose to collect more data or conduct a more complex assessment in order to verify the result before actions are taken. An initial analysis may also be used to identify insignificant exposure pathways that do not require further consideration.

In many cases, deterministic techniques may be more desirable than probabilistic methods, particularly for such early analyses that are often under time and resource constraints, because probabilistic methods can be more complex, time-consuming, and costly. On the other hand, risk managers may find that more sophisticated techniques, including probabilistic methods, are valuable in providing certain detailed information about the risks in the exposed population, to explore the uncertainty in the true, but unknown risk to an individual, or for systematically analyzing variability, uncertainty, pathways of exposure, or alternative models. The risk assessor and risk manager must consider the utility of the risk assessment result and determine the value added by each assessment choice that increases the time, cost, and complexity of the assessment.

Ultimately, a risk assessment is conducted to gain insight into the exposures and risks associated with a given scenario. See section VI.F. of the guidelines (CPSC 1992). Each assessment should be approached on a case-by-case basis, consistent with the requirements of the risk assessor and risk manager. Regardless of the risk analysis approach, the quality of the assessment depends on the quality and availability of relevant data.

In general, for a given body of knowledge, a deterministic assessment that is based predominantly on central tendency values for each of the input variables (*e.g.,* a best estimate of the available data, such as a mean or median), may provide results similar to a probabilistic assessment that is based on the same underlying information. However, risk analysts must be aware of the effects of decisions regarding the use of the available data and assumptions. For example, a deterministic analysis that uses multiple protective values rather than central values may lead to unintentionally precautious results, *i.e.,* compounding safety factors. In addition, for a distribution of data that is skewed to the right, the mean will be represented by a value in the right tail and could be considerably larger than the median. In such a case, the mean could also be considered a protective value.

The primary advantage of a probabilistic approach is the generation of information on the distribution of exposure and risk in a population, in addition to estimates of the average exposure and risk. This provides information on the range of exposures, including highly exposed individuals. However, the risk analyst must consider that sparse data or a poorly fitting distribution to the data for one or more model inputs could lead to inappropriate conclusions about the resulting distribution, particularly at the tails of the distribution, which may be most sensitive to deficiencies in the data. Further, a probabilistic model may be sensitive to correlations between input variables (*e.g.,* body weight and body surface area). Discussion of the presence of correlations and dependence among variables and their effects on the output should be included in the assessment.

Another advantage of probabilistic techniques is the ability to derive confidence intervals for exposure estimates. Thus, in addition to estimating the mean, median, and 95th percentiles of exposure, one may also estimate confidence intervals for these

estimates, expressed as X ± Y, which provides a measure of uncertainty in the estimated exposure. It also gives the risk assessor and risk manager information on the reliability of exposure estimates. Typically, the confidence intervals will be larger in the tails of the distribution, *i.e.,* confidence intervals for the 95th or 99th percentile of the distribution may be larger than the confidence interval about the mean. Therefore, whenever possible, methodology that permits the estimation of confidence intervals should be applied.

Currently, probabilistic techniques are used primarily in estimating exposure, while single point estimates are derived to describe the dose-response (*i.e.,* unit risk for carcinogens; ADI for non-carcinogens). The application of probabilistic methods to deriving unit risks and ADIs is not presently in widespread use, although this has been encouraged by the National Research Council (NRC 2009).

A distinct issue, but related to analysis of uncertainty, is sensitivity analysis. Sensitivity analysis is used to identify variables that have the largest effect on the assessment output, and general approaches and statistical techniques have been developed for both deterministic and probabilistic analyses. It is often useful to know if small changes in the values for some variables result in relatively large changes in the output. For example, such an analysis may be used to identify areas of research that could improve future risk assessments. Sensitivity analysis may also be used to focus on specific subpopulations or exposure scenarios or to identify the most important routes of exposure.

Such techniques also are useful for providing additional information in a deterministic assessment. That is, a separate sensitivity analysis can be used in conjunction with a deterministic approach to characterize the range of the most likely estimates of exposure and risk (*e.g.,* one technique is to vary key input variables, one at a time, throughout their reasonable range of values, while holding other inputs constant).

Recent exposure and risk assessments conducted by CPSC staff have used both deterministic and probabilistic methods based on the factors discussed above. For example, staff used probabilistic techniques to estimate the exposure and risk from oral intake of diisononyl phthalate by children from mouthing soft plastic toys and other objects, based on the strength of the available data (Babich 2002; Babich et al. 2004; Babich et al. 2020; Greene 2002). Yet staff used a deterministic approach with a separate uncertainty analysis to assess children's exposure to arsenic from wooden playground equipment treated with chromated copper arsenate (Hatlelid 2003), because staff concluded that the data for several key input variables were insufficient to support a probabilistic analysis. In this case, mainly central tendency values were used to estimate the exposure, and a separate uncertainty analysis provided additional information about the likely range of exposure.

Section VI.F.4.b.i. of the guidelines (CPSC 1992) states that a carcinogenic risk of one per million or less is the appropriate level for defining acceptable risk; *i.e.,* when exposure to an agent occurs, the exposed individual has an estimated excess risk of one chance in a million of developing cancer during his/her lifetime. In a deterministic analysis, one per million is compared directly with the risk value that results from the analysis. Section VI.F.1.d. of the guidelines also states that in most cases the best estimate of exposure, rather than a protective estimate, is acceptable.

Probabilistic analyses, however, result in distributions of exposure and risk. While there are no generally accepted guidelines for interpretation of results from probabilistic analyses for carcinogens, this topic has received attention (Burmaster 1996; Thompson 2002; NRC 2009). Thompson cautioned against setting ''bright-line'' criteria for use in any context, and Burmaster also argued that the risk manager must consider all the characteristics of the distribution resulting from the probabilistic assessment and not just a single point or summary statistic. As an example of how one might evaluate probabilistic results, Burmaster suggested that one might consider the skewness of the resulting risk distribution; whether the median of the distribution exceeds the one per million acceptable risk level; whether the mean exceeds one per one hundred thousand; and whether the 95th percentile exceeds one per ten thousand.

CPSC staff agrees that it generally is appropriate to consider all of the characteristics of the risk distribution (*e.g.,* the mean, median, and upper bounds values and the shape of the distribution) in judging whether or not the results represent an acceptable risk. Because of the complexity of probabilistic analyses and the diversity of possible probabilistic risk assessment results, staff assesses that it would be difficult to impose a rigid procedure for interpreting the results of probabilistic assessments. Staff recommends, however, that the one per million acceptable risk level for carcinogens currently defined in the guidelines generally should also serve as a guide for interpreting probabilistic risk assessment results. Because staff generally uses best estimates for exposure rather than upper bounds, staff assesses that interpretation of probabilistic results should be based in part on the relationship of the central tendency estimate of the resulting distribution to the one per million acceptable risk level. However, upper bound estimates of exposure (*e.g.,* 95th percentile) may provide useful information for highly exposed individuals.

Section VI.F.4.b.ii. (CPSC 1992) specifies a process for evaluating the acceptable daily intake (ADI) for neurotoxicological and developmental/reproductive agents. Staff uses these guidelines for other non-cancer effects, as well. The use of the ADI in a deterministic assessment is straightforward—the estimated exposure is compared with the ADI. As is the case with cancer risk assessment, there are no standard guidelines for interpretation of results from probabilistic analyses of non-cancer effects. Following the reasoning for cancer assessments given above, staff recommends that interpretation of probabilistic results for non-cancer effects should be based in part on comparing the central tendency estimate of the outcome to the acceptable daily intake, similar to the case for deterministic assessments. However, upper bound estimates of exposure (*e.g.,* 95th percentile) may provide useful information for highly exposed individuals.

Because the guidelines are not binding rules, they are meant to be flexible and amenable to expert judgment, as well as continuing scientific advances. The guidance for interpretation of both cancer and non-cancer exposure and risk are intended to facilitate the assessment process, but in practice, risk assessors and risk managers will consider the specific information in each case in defining acceptable exposure and risk.

C. Summary

The following supplements the guidance on exposure assessment in the CPSC Chronic Hazard Guidelines at 57 FR 46644 (Oct. 9, 1992) in section VI.F.1. It does not supersede the 1992 guidance; rather, it provides guidance on the use of probabilistic methods as an alternative method for exposure assessment.

Risk assessments may incorporate uncertainty (the lack of knowledge in the underlying science or in the choice

of mathematical model) and variability (inherent differences due to heterogeneity or diversity in the population or exposure variable). The discussion may be qualitative or include quantitative estimates of uncertainty and variability. While variability and uncertainty are distinct issues and should be considered separately in each analysis, in practice, the available data may not be sufficient to distinguish between them.

Risk assessments may be based on deterministic or probabilistic modeling. Probabilistic modeling uses probability distributions for some or all inputs in conjunction with statistical techniques such as Monte Carlo analysis, and results in a distribution of exposure or risk estimates, providing quantification of uncertainty and variability. Deterministic modeling enters point estimates for the model's inputs and results in a point estimate of the exposure or risk. Separate uncertainty analysis may be used with a deterministic approach to characterize the range of the most likely exposure and risk.

Because exposure and risk assessments are conducted for different reasons, the ultimate use of the assessment results will help determine the methodological approaches and techniques to be used. The choice of approach may be based on considerations of the available scientific information, institutional policies, available time and resources, and limitations of the methods. For example, deterministic techniques may be appropriate for initial analyses that are often under time and resource constraints; however, the use of multiple protective values in a deterministic analysis may lead to unintentionally protective results, *i.e.,* compounding safety factors. A probabilistic assessment may be used to generate information on the distribution of exposure and risk in a population or to explore the uncertainty in the true, but unknown risk to an individual, but the risk assessor must consider that sparse data or poorly fitting distributions to the data for one or more model inputs could lead to inappropriate conclusions about the results, particularly at the tails of the distribution, which may be most sensitive to deficiencies in the data. A probabilistic model may be sensitive to correlations between input variables; the presence of correlations and dependence among variables and their effects on the output should be considered.

A carcinogenic risk of one per million or less is the guidelines' default level for defining acceptable risk (16 CFR 1500.135(d)(4)(i)). In a deterministic analysis, one per million is compared directly with the risk value that results from the analysis. Interpretation of probabilistic results should be based in part on the relationship of the central tendency estimate (*e.g.,* mean or median, as appropriate for the specific distribution) to the one per million acceptable risk level, but all characteristics of the resulting distribution should be considered.

For assessment of non-carcinogens in a deterministic assessment, the exposure estimate is compared directly with the ADI, or the hazard index (HI) is calculated as the ratio of the estimated exposure to the ADI (HI greater than one means that the exposure may be hazardous; HI less than one represents negligible risk). Probabilistic results should be interpreted in part by comparing the central tendency estimate to the acceptable daily intake, but all characteristics of the resulting distribution should be considered.

The guidance for interpretation of both cancer and non-cancer exposure and risk are intended to facilitate the assessment process, but in practice, risk assessors and risk managers will consider the specific information in each case in defining acceptable exposure and risk.

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Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–08604 Filed 4–22–24; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Business Board; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Deputy Secretary of Defense, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Business Board (''the Board'') will take place.

DATES: Closed to the public May 7, 2024 from 9:00 a.m. to 7:05 p.m. and closed to the public May 8, 2024 from 8:30 a.m. to 11:50 a.m. All Eastern time.

ADDRESSES: The closed meeting will be held in room B7 of the Pentagon Library Conference Center, Room 4D728 in the Pentagon, and the U.S. Naval Research Laboratory, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Cara Allison Marshall, Designated Federal Officer (DFO) of the Board in writing at Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155; or by email at *cara.l.allisonmarshall.civ@mail.mil;* or by phone at 703–614–1834.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), section 552b of title 5, U.S.C. (commonly known as the ''Government in the Sunshine Act''), and 41 Code of Federal Regulations (CFR) section 102–3.140 and 102–3.150.

Purpose of Meeting: The mission of the Board is to examine and advise the Secretary and Deputy Secretary of Defense on overall DoD management and governance. The Board provides independent, strategic-level, private sector and academic advice and counsel on enterprise-wide business management approaches and best practices for business operations and achieving National Defense goals.

Agenda: The Board will begin in closed session on May 7 from 9:00 a.m. to 7:05 p.m. The DFO will begin the closed session followed by a welcome by Board Chair, Hon. Deborah James. The Board will receive a classified discussion on Implementing Emerging Technologies to Create Operational Strategic Effects from Mr. Jay Dryer, Director, Strategic Capabilities Office. This discussion will focus on using existing DoD tools and processes to adapt developing technology to key operational challenges in the National Defense Strategy (NDS). Next, the Board will receive a classified discussion on Current Affairs from Hon. Lloyd Austin, Secretary of Defense. This session is expected to focus on the state of the current global security environment and its implications for current and future business operations. The Board will receive a classified briefing on Naval Research Lab (NRL) Operations at the U.S. NRL, followed by a classified tour. This tour and discussion will explore management constructs unique to NRL's mission and personnel, to include developing and managing talent and communicating across a diverse workforce. This portion of the meeting will cover how NRL partners with industry to fulfill their mandate and demonstrates capabilities made possible by NRL's organizational constructs and authorities. The Board Chair, Hon Deborah James and Deputy Secretary, Hon. Kathleen Hicks will provide remarks, followed by a classified update on Industry Partnerships with the Director of Information Systems Agency (DISA), Lt Gen Robert J. Skinner, Director of DISA and the Commander of the Joint Force Headquarters-DoD Information Network. The Director will offer an overview of DISA's partnerships with various stakeholders to bolster warfighter capabilities, including how DISA is developing global situational awareness and assessing the threat against DISA operations and assets. He will discuss unique challenges of managing a DoD Agency and Field Activity, as well as provide insights on recommendations from the February 2023 DBB IT User Experience Study. The DFO will adjourn the closed session. The Board will reconvene in closed session May 8 from 8:30 a.m. to 11:50 a.m. in room B7 of the Pentagon Library Conference Center. The DFO will begin the closed session followed by a welcome by the Board Chair. The Board will receive a classified discussion on Growing Production Capacity for Crises from Dr. Erin Simpson, Director, Joint Production Accelerator Cell, Office of the Under Secretary of Defense for Acquisition & Sustainment. The conversation is expected to delve into actions the DoD is taking to prioritize resources and to create a modern, resilient defense industrial ecosystem designed to deter United States adversaries and meet the production demands posed by evolving threats.

Dr. Simpson will elaborate on the obstacles confronting the DoD in building resilient supply chains. Next, the Board will receive a classified discussion on Emerging Global Threats, including the Supply Chain, and their Potential Implications for the NDS from MG Joseph ''JP'' McGee, U.S. Army, Director for Strategy, Plans & Policy, J5. This discussion will focus on strategic proactiveness to ensure adaptability, resilience, and continued effectiveness in an ever-evolving security landscape and on how the DoD can partner with industry before and during crises. After a short break, the Board will receive their final classified discussion on Making DoD Work Attractive to Non-Traditional Companies from Hon. Kathleen Hicks. The Deputy Secretary will share successes the DoD has realized in becoming a better partner for non-traditional defense companies, along with how combinations of traditional and non-traditional companies are working together to accelerate capability development and delivery. The DFO will adjourn the closed session. The latest version of the agenda will be available on the Board's website at: *https://dbb.dod.afpims.mil/Meetings/Meeting-May-7-8-2024/*.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, it is hereby determined that the May 7–8 meeting of the Board will include classified information and other matters covered by 5 U.S.C. 552b(c)(1) and that, accordingly, the meeting will be closed to the public. This determination is based on the consideration that it is expected that discussions throughout the meeting will involve classified matters of national security. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the meeting. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the Board's findings and recommendations to the Secretary of Defense and the Deputy Secretary of Defense.

Written Comments and Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and 5 U.S.C. 1009(a)(3), the public or interested organizations may submit written comments or statements to the Board in response to the stated agenda of the meeting or regarding the Board's mission in general. Written comments or statements should be submitted to

Ms. Cara Allison Marshall, the DFO, via electronic mail (the preferred mode of submission) at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The DFO must receive written comments or statements submitted in response to the agenda set forth in this notice by close of business Friday, May 3, 2024, to be considered by the Board. The DFO will review all timely submitted written comments or statements with the Board Chair and ensure the comments are provided to all members of the Board before the meeting. Written comments or statements received after this date may not be provided to the Board until its next scheduled meeting. Please note that all submitted comments and

statements will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Dated: April 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–08589 Filed 4–22–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Comprehensive Literacy State Development

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2024 for the Comprehensive Literacy State Development (CLSD) program, Assistance Listing Number 84.371C. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES:

Applications Available: April 23, 2024.

Deadline for Notice of Intent to Apply: May 13, 2024.

Deadline for Transmittal of Applications: June 24, 2024.

Deadline for Intergovernmental Review: August 21, 2024.

Pre-Application Webinar Information: The Department will hold a pre-application meeting via webinar for prospective applicants. For information about the pre-application webinar, visit the CLSD website at: *https://oese.ed.gov/offices/office-of-discretionary-grants-support-services/well-rounded-education-programs/striving-readers-comprehensive-literacy-srcl-formula-grants-84-371a-for-state-literacy-teams/.*

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045), and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Michael Berry, U.S. Department of Education, 400 Maryland Avenue SW, Room 4C128, Washington, DC 20202–6450. Telephone: (202) 453–7088. Email: *michael.berry@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The CLSD program awards competitive grants to advance literacy skills through the use of evidence-based (as defined in this notice) practices, activities, and interventions, including pre-literacy skills, reading, and writing, for children from birth through grade 12, with an emphasis on disadvantaged children, including children living in poverty, English learners (as defined in this notice), and children with disabilities (as defined in this notice).

Background: The Department's ''Raise the Bar: Lead the World'' initiative is a call to action to transform preschool through grade 12 education and beyond, and to unite education leaders at all levels around evidence-based strategies that advance educational equity and excellence for all students.[1] Raising the bar in education focuses on building the skills that all students need to thrive inside and outside of school, and supporting students to excel in the classroom, in their careers, and in their communities.

Specifically, the Department is focused on improving student achievement, including in math and reading, as highlighted across Administration and Department efforts for the past several years. Building on the Administration's previous efforts, in January 2024, the Administration announced its Improving Student Achievement Agenda,[2] which aims to drive proven strategies that will support academic success for every child in school. The strategies and evidence discussed in the Improving Student Achievement Agenda focus on (1) increasing student attendance; (2) providing high-dosage tutoring; and (3) increasing summer learning and extended or afterschool learning time. These strategies and the broader Improving Student Achievement Agenda, including a focus on core academic instruction, are well aligned with the CLSD program purpose of improving literacy outcomes, and the new funding to be released through the FY 2024 CLSD competition will help accelerate and scale up sustainable adoption of evidence-based strategies that we expect will improve student literacy outcomes in the school years ahead.

Through the FY 2024 CLSD competition, the Department encourages State educational agencies (SEAs) to focus on evidence-based activities that provide explicit intervention and support in reading and writing for children from birth to grade 12, including activities that have been implemented in response to identified literacy gaps and that have positive outcome data. SEAs should take into consideration the resources of the What Works Clearinghouse,[3] including the literacy-focused Practice Guides and Intervention Reports on the most effective strategies for supporting student literacy and that are appropriate for the grade, age, and developmental level of the student. Highly effective, evidence-based literacy strategies covered in the Practice Guides, for example, include developing awareness of the segments of sounds in speech and how they link to letters; teaching students to decode words, analyze word parts, and write and recognize words; building students' comprehension and decoding skills so they can read complex multisyllabic words; and providing purposeful fluency-building activities to help students read effortlessly. The What Works Clearinghouse Intervention Reports provide a summary of the highest quality research to help SEA and school district personnel identify the literacy interventions with the strongest evidence bases. The Department encourages SEAs to consult these Intervention Reports to inform their proposals and the technical assistance they provide to school districts. Another resource the Department encourages SEAs to use is the Comprehensive Literacy State Development (CLSD) National Literacy Center,[4] which has a

[1] *https://www.ed.gov/raisethebar/.*

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2024/01/17/fact-sheet-biden-harris-administration-announces-improving-student-achievement-agenda-in-2024/.*

[3] The Department provides several resources related to evidence-based practices and interventions in literacy. For example, the Institute of Education Sciences' What Works Clearinghouse (*https://whatworks.ed.gov*) has ten practice guides that offer evidence-based recommendations on literacy and/or writing that are applicable to preschool, elementary, and secondary school settings. Additionally, WWC Intervention Reports review the strength of evidence for branded interventions supporting literacy (and other) outcomes. Other Department resources, including those related to the Best Practices Clearinghouse (*https://bestpraacticesclearinghouse.gov*) and Raise the Bar (*https://ed.gov/raisethebar/academic-success*), may also be of interest to some applicants.

[4] *https://literacycenter.ed.gov/.*

website that offers information and resources to support States in creating or revising State literacy plans and to identify opportunities and strategies for providing evidence-based literacy coaching for teachers.

This competition includes four competitive preference priorities that highlight key policies on which States may focus their proposed projects. First, the Department gives competitive preference to projects that incorporate SEA partnerships with institutions of higher education (IHEs). Strong partnerships with IHEs strengthen educator (as defined in this notice) preparation programs and high-quality professional development (as defined in this notice) for educators, resulting in more effective comprehensive State literacy programs. Second, the Department gives competitive preference to applications that propose projects that are designed to address the impacts of the COVID–19 pandemic using evidence-based instructional approaches and supports to successfully meet challenging academic content standards without contributing to tracking or remedial courses.

Third, the Department gives competitive preference to applications that propose projects designed to promote education equity and adequacy in resources and opportunity for underserved students (as defined in this notice). In responding to this priority, SEAs are encouraged to consider how projects can assess the literacy needs of underserved students, including multilingual learners, to support the screening and identification of reading disabilities (*e.g.,* dyslexia), and evidence-based instructional approaches tailored to students' specific needs. Fourth, the Department gives competitive preference to applications that propose projects that support students and their families at key transitional stages in their education by ensuring coordinated, high-quality professional development for educators in these transitional stages. The Department is interested in projects that include high-quality, evidence-based professional development focused on alignment between early childhood and elementary settings as well as older students who are reading significantly below grade level. Effective comprehensive literacy programs include strong collaboration between early childhood, elementary, and secondary school educators.

Through an invitational priority, the Department encourages projects that support effective transition practices, continuity of services and supports, and aligned instruction for students as they transition from preschool and other early childhood settings into kindergarten and from kindergarten into the early grades, which includes supporting efforts that promote strong foundational literacy skills that undergird early literacy and early math success. The Department also encourages projects that support acceleration strategies for improving literacy for secondary school students who are reading at least 1–2 years below grade level. Additionally, the Department would like to highlight practices that have yielded positive results so that they may be shared with the wider literacy field.

Priorities: This notice contains four competitive preference priorities and one invitational priority. Competitive Preference Priority 1 is from section 2222(f)(2) of the ESEA. Competitive Preference Priorities 2, 3, and 4 are from the Secretary's Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the **Federal Register** on December 10, 2021 (86 FR 70612) (Supplemental Priorities).

Competitive Preference Priorities: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award an additional 2 points to an application that meets subpart (a) of Competitive Preference Priority 1 and an additional 2 points to an application that meets subpart (b) of Competitive Preference Priority 1; we award up to an additional 2 points to an application, depending on how well the application addresses Competitive Preference Priority 2; we award up to an additional 2 points to an application, depending on how well the application addresses Competitive Preference Priority 3; and we award up to an additional 2 points to an application, depending on how well the application addresses Competitive Preference Priority 4. An application may receive a total of up to 10 additional points under these competitive preference priorities.

These priorities are:

Competitive Preference Priority 1—Coordination with Institutions of Higher Education. (0, 2, or 4 points)

Under this priority, an applicant must demonstrate how it will use the State-level reservation under section 2222(f)(2) of the ESEA to carry out one or more of the following activities:

(a) Coordinate with IHEs in the State to provide recommendations to strengthen and enhance pre-service courses for students preparing to teach children from birth through grade 12 in explicit, systematic, and intensive instruction in evidence-based literacy methods. (2 points)

(b) Review and update, in collaboration with teachers and IHEs, State licensure or certification standards in the area of literacy instruction in early education through grade 12. (2 points)

Competitive Preference Priority 2—Addressing the Impact of COVID–19 on Students, Educators, and Faculty. (0 to 2 points).

Projects that are designed to address the impacts of the COVID–19 pandemic, including impacts that extend beyond the duration of the pandemic itself, on the students most impacted by the pandemic, with a focus on underserved students and the educators who serve them, through using evidence-based instructional approaches and supports, such as professional development, coaching, ongoing support for educators, high-quality tutoring, expanded access to rigorous coursework and content across K–12, and expanded learning time to accelerate learning for students in ways that ensure all students have the opportunity to successfully meet challenging academic content standards without contributing to tracking or remedial courses.

Competitive Preference Priority 3—Promoting Equity in Student Access to Educational Resources and Opportunities. (0 to 2 points)

Projects that are designed to promote educational equity and adequacy in resources and opportunity for underserved students—

(1) In one or more of the following educational settings:

(i) Early learning programs.

(ii) Elementary school.

(iii) Middle school.

(iv) High school.

(v) Out-of-school-time settings.

(vi) Alternative schools and programs.

(vii) Juvenile justice system or correctional facilities.

(viii) Adult learning.[5]

(2) That examines the sources of inequity and inadequacy and implement responses, and that may include one or more of the following:

(i) Establishing, expanding, or improving learning environments for multilingual learners, and increasing public awareness about the benefits of fluency in more than one language and

[5] CLSD grantees must subgrant 95 percent of their funds to serve the following age/grade bands: 15 percent for birth through kindergarten entry; 40 percent for kindergarten through grade 5; and 40 percent for grades 6 through 12. CLSD funds may be used for adult learning in settings where the adult learners are earning their high school diplomas.

how the coordination of language development in the school and the home improves student outcomes for multilingual learners.

(ii) Expanding access to high-quality early learning, including in school-based and community-based settings, by removing barriers through implementation of programs that are inclusive with regard to race, ethnicity, culture, language, and disability status.

Competitive Preference Priority 4—Supporting a Diverse Educator Workforce and Professional Growth To Strengthen Student Learning. (0 to 2 points)

Projects that are designed to increase the proportion of well-prepared, diverse, and effective educators serving students, with a focus on underserved students, through supporting effective instruction and building educator capacity by providing high-quality job-embedded professional development opportunities focused on supporting students and their families at key transitional stages in their education as they enter into one or more of the following:

(a) Early learning programs.

(b) Elementary school.

(c) Middle school.

(d) High school.

Invitational Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Supporting Effective Transition Practices, Continuity of Services and Supports, and Aligned Instruction, Including for Students from Preschool and Other Early Childhood Settings into Kindergarten; from Kindergarten into the Early Grades; and in Elementary and Secondary Education.

Projects that—

(a) Include developmentally appropriate practices that support cross-sector collaboration and family engagement across early learning and early elementary grades to support continuity of relationships and services from preschool through grade three, including practices that promote strong foundational literacy skills that undergird early literacy and early math success;

(b) Increase and improve educational opportunities for students and promote academic recovery through aligning the instruction between preschool and grade three and supporting educators and school leaders; and

(c) Increase and improve educational opportunities and outcomes for secondary school students who are reading below or significantly below grade level and promote their increased literacy through developmentally appropriate practices, including practices that support accelerated growth in literacy skills.

Application Requirements: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, applicants must submit an application that meets the following application requirements from section 2222 of the ESEA (20 U.S.C. 6642):

(a) *State Needs Assessment.*

An SEA must include a needs assessment that analyzes literacy needs across the State and in high-need schools (as defined in this notice) and LEAs that serve high-need schools, including identifying the most significant gaps in literacy proficiency and inequities in student access to effective teachers of literacy, considering each of the subgroups of students, as defined in section 1111(c)(2) of the ESEA.

(b) *State Comprehensive Literacy Plan.*

An SEA must include a description of how, in collaboration with its State literacy team, if applicable, it will develop a State comprehensive literacy instruction (as defined in this notice) plan or will revise and update an already existing State comprehensive literacy instruction plan.

(c) *State Implementation Plan.*

An SEA must include an implementation plan that includes a description of how it will carry out the State activities described in section 2222(f) of the ESEA.

(d) *State Agency Early Childhood Program Collaboration.*

An SEA must collaborate with the State agency responsible for administering early childhood education programs and the State agency responsible for administering child-care programs in the State in writing and implementing the early childhood education portion of the grant application submitted for the CLSD program.

(e) *Assurances.*

An SEA must include in its application the following assurances:

(1) *State Funding Allocations.*

(a) An SEA must assure that it will subgrant not less than 95 percent of grant funds to eligible entities (as defined in this notice), based on their needs assessment and a competitive application process, for comprehensive literacy instruction programs according to the funding allocations in Program Requirement (a).

(b) An SEA must assure it will use grant funds described in section 2222(f)(1) for comprehensive literacy instruction programs as follows:

(i) Not less than 15 percent of such grant funds must be used for State and local programs and activities pertaining to children from birth through kindergarten entry.

(ii) Not less than 40 percent of such grant funds must be used for State and local programs and activities, allocated equitably among the grades of kindergarten through grade 5.

(iii) Not less than 40 percent of such grant funds must be used for State and local programs and activities, allocated equitably among grades 6 through 12.

(2) *Serving Low-Income and High-Need Students.*

An SEA must assure that it will give priority in awarding subgrants to eligible entities that—

(i) Serve children from birth through age 5 who are from families with income levels at or below 200 percent of the Federal poverty line (as defined in this notice); or

(ii) Are LEAs serving a high number or percentage of high-need schools.

(3) *Geographic Diversity.*

An SEA must assure that it will provide subgrants to eligible entities serving a diversity of geographic areas, giving priority to entities serving greater numbers or percentages of children from low-income families.

Program Requirements: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following program requirements apply. These program requirements are from sections 2222–2225 and 2301 of the ESEA.

(a) *State Funding Allocations.*

(1) Grantees must use not less than 95 percent of grant funds to award subgrants to eligible entities, based on their needs assessment and a competitive application process;

(2) Grantees must subgrant funds as follows:

(i) Not less than 15 percent of the funds awarded to subgrantees must be used for State and local programs and activities pertaining to children from birth through kindergarten entry;

(ii) Not less than 40 percent of the funds awarded to subgrantees must be used for State and local programs and activities, allocated equitably among the grades of kindergarten through grade 5; and

(iii) Not less than 40 percent of the funds awarded to subgrantees must be

used for State and local programs and activities, allocated equitably among grades 6 through 12.

(b) *State-Level Activities.*

(1) A grantee may reserve not more than 5 percent of the CLSD funds it receives for activities identified through the needs assessment and comprehensive literacy plan, including, at a minimum, the following activities:

(i) Providing technical assistance, or engaging qualified providers to provide technical assistance, to eligible entities to enable the eligible entities to design and implement literacy programs.

(ii) Coordinating with IHEs in the State to provide recommendations to strengthen and enhance pre-service courses for students preparing to teach children from birth through grade 12 in explicit, systematic, and intensive instruction in evidence-based literacy methods.

(iii) Reviewing and updating, in collaboration with teachers and IHEs, State licensure or certification standards in the area of literacy instruction in early education through grade 12.

(iv) Making publicly available, including on the SEA's website, information on promising instructional practices to improve child literacy achievement.

(v) Administering and monitoring the implementation of subgrants by eligible entities.

(2) After making awards to subgrantees and carrying out the State-level activities described in this notice, an SEA may use any remaining amount to carry out one or more of the following activities:

(i) Developing literacy coach training programs and training literacy coaches.

(ii) Administration and evaluation of CLSD activities.

(3) Collaboration requirement.

A grantee must collaborate with the State agency responsible for administering early childhood education programs, the State agency responsible for administering child care programs, and, if applicable, the State Advisory Council on Early Childhood Education and Care designated or established pursuant to section 642(b(1)(A)(i) of the Head Start Act, in making and implementing subgrants under the early childhood education portion of the CLSD program, described in section 2222(d)(2)(D)(i).

Note: Section 2222(d)(1) of the ESEA specifically references childcare and early childhood programs within a State. Since the CLSD service population encompasses children from birth and includes pre-literacy services, applicants may collaborate with the State agencies administering the Part C program for infants and toddlers under the Individuals with Disabilities Education Act (IDEA) in their program planning, as some children being served under Part C would likely benefit from CLSD services.

(c) *Requirements That Apply to Subgrants to Eligible Entities in Support of Birth through Kindergarten Entry Literacy.*

(1) Subgrantee application requirements.

An eligible entity desiring to receive a subgrant under CLSD must submit an application to the SEA, at such time, in such manner, and containing such information as the SEA may require. Such application must include a description of—

(i) How the CLSD funds will be used to enhance the language and literacy development and school readiness of children, from birth through kindergarten entry, in early childhood education programs, which must include an analysis of data that support the proposed use of CLSD funds;

(ii) How the CLSD funds will be used to prepare and provide ongoing assistance to staff in the programs, including through high-quality professional development;

(iii) How the activities assisted with the CLSD funds will be coordinated with comprehensive literacy instruction at the kindergarten through grade 12 levels; and

(iv) How the CLSD funds will be used to evaluate the success of the activities assisted under the subgrant in enhancing the early language and literacy development of children from birth through kindergarten entry.

(2) Priority.

In awarding subgrants to eligible entities in support of birth through kindergarten entry, sections 2222(d)(2)(E) and 2223(c) of the ESEA require that an SEA must provide an assurance that it will—

(i) Give priority to an eligible entity that will use CLSD funds to implement evidence-based activities;

(ii) Give priority to an eligible entity that will use CLSD funds to serve children from birth through age 5 who are from families with income levels at or below 200 percent of the Federal poverty line or is a local educational agency (LEA) serving a high number or percentage of high-need schools.

(3) Duration.

The term of a subgrant must be determined by the grantee and must not exceed five years.

(4) Sufficient size and scope.

Each subgrant must be of sufficient size and scope to allow the eligible entity to carry out high-quality early literacy initiatives for children from birth through kindergarten entry.

(5) Local uses of funds.

An eligible entity that receives a subgrant from the SEA must use the CLSD funds, consistent with the entity's approved application, to—

(i) Carry out high-quality professional development opportunities for early childhood educators, teachers, principals, other school leaders (as defined in this notice), paraprofessionals, specialized instructional support personnel, and instructional leaders;

(ii) Train providers and personnel to develop and administer evidence-based early childhood education literacy initiatives; and

(iii) Coordinate the involvement of families, early childhood education program staff, principals, other school leaders, specialized instructional support personnel (as appropriate), and teachers in literacy development of children served under CLSD.

(d) *Requirements That Apply to Subgrants to Eligible Entities in Support of Kindergarten through Grade 12 Literacy.*

(1) Subgrantee application requirements.

An eligible entity desiring to receive a subgrant from the SEA under the CLSD program must submit an application to the SEA at such time, in such manner, and containing such information as the SEA may require. Such application must include, for each school that the eligible entity identifies as participating in a CLSD program, the following information:

(i) A description of the eligible entity's needs assessment conducted to identify how CLSD funds will be used to inform and improve comprehensive literacy instruction at the school.

(ii) How the school, the LEA, or a provider of high-quality professional development will provide ongoing high-quality professional development to all teachers, principals, other school leaders, specialized instructional support personnel (as appropriate), and other instructional leaders served by the school.

(iii) How the school will identify children in need of literacy interventions or other support services.

(iv) An explanation of how the school will integrate comprehensive literacy instruction into a well-rounded education (as defined in this notice).

(v) A description of how the school will coordinate comprehensive literacy instruction with early childhood education programs and activities and after-school programs and activities in the area served by the LEA.

(2) Priority.

In awarding subgrants to eligible entities, sections 2222(d)(2)(E) and 2223(c) of the ESEA require that an SEA must provide an assurance that it will—

(i) Give priority to an LEA that will use CLSD funds to implement evidence-based activities; and

(ii) Give priority to an LEA serving a high number or percentage of high-need schools.

(3) Duration.

The term of a subgrant must be determined by the grantee and must not exceed five years.

(4) Sufficient size and scope.

Each subgrant must be of sufficient size and scope to allow the eligible entity to carry out high-quality comprehensive literacy instruction in each grade level for which the CLSD funds are provided.

(5) Local uses of funds for kindergarten through grade 5.

An eligible entity that receives a subgrant from the SEA under the CLSD program must use the CLSD funds to carry out the following activities pertaining to children in kindergarten through grade 5:

(i) Developing and implementing a comprehensive literacy instruction plan across content areas for such children that—

(A) Serves the needs of all children, including children with disabilities and English learners, especially children who are reading or writing below grade level;

(B) Provides intensive, supplemental, accelerated, and explicit intervention and support in reading and writing for children whose literacy skills are below grade level; and

(C) Supports activities that are provided primarily during the regular school day but that may be augmented by after-school and out-of-school time instruction.

(ii) Providing high-quality professional development opportunities for teachers, literacy coaches, literacy specialists, English as a second language specialists (as appropriate), principals, other school leaders, specialized instructional support personnel, school librarians, paraprofessionals, and other program staff.

(iii) Training principals, specialized instructional support personnel, and other LEA personnel to support, develop, administer, and evaluate high-quality kindergarten through grade 5 literacy initiatives.

(iv) Coordinating the involvement of early childhood education program staff, principals, other instructional leaders, teachers, teacher literacy teams, English as a second language specialists (as appropriate), special educators, school personnel, and specialized instructional support personnel (as appropriate) in the literacy development of children served.

(v) Engaging families and encouraging family literacy experiences and practices to support literacy development.

(6) Local uses of funds for grades 6 through 12.

An eligible entity that receives a subgrant from the SEA under CLSD must use CLSD funds to carry out the following activities pertaining to children in grades 6 through 12:

(i) Developing and implementing a comprehensive literacy instruction plan across content areas for such children that—

(A) Serves the needs of all children, including children with disabilities and English learners, especially children who are reading or writing below grade level;

(B) Provides intensive, supplemental, accelerated, and explicit intervention and support in reading and writing for children whose literacy skills are below grade level; and

(C) Supports activities that are provided primarily during the regular school day but that may be augmented by after-school and out-of-school time instruction.

(ii) Training principals, specialized instructional support personnel, school librarians, and other LEA personnel to support, develop, administer, and evaluate high-quality comprehensive literacy instruction initiatives for grades 6 through 12.

(iii) Assessing the quality of adolescent comprehensive literacy instruction as part of a well-rounded education.

(iv) Providing time for teachers to meet to plan evidence-based adolescent comprehensive literacy instruction to be delivered as part of a well-rounded education.

(v) Coordinating the involvement of principals, other instructional leaders, teachers, teacher literacy teams, English as a second language specialists (as appropriate), paraprofessionals, special educators, specialized instructional support personnel (as appropriate), and school personnel in the literacy development of children served.

(7) Additional local allowable uses of funds for kindergarten through grade 12.

An eligible entity that receives a subgrant from an SEA under CLSD may, in addition to carrying out the activities described in paragraphs 5 and 6 of this requirement, use subgrant funds to carry out the following activities pertaining to children in kindergarten through grade 12:

(i) Recruiting, placing, training, and compensating literacy coaches.

(ii) Connecting out-of-school learning opportunities to in-school learning in order to improve children's literacy achievement.

(iii) Training families and caregivers to support the improvement of adolescent literacy.

(iv) Providing for a multi-tier system of supports (as defined in this notice) for literacy services.

(v) Forming a school literacy leadership team to help implement, assess, and identify necessary changes to the literacy initiatives in 1 or more schools to ensure success.

(vi) Providing time for teachers (and other literacy staff, as appropriate, such as school librarians or specialized instructional support personnel) to meet to plan comprehensive literacy instruction.

(e) *Supplement not Supplant.*

Grantees must use CLSD funds to supplement, and not supplant, non-Federal funds that would otherwise be used for activities authorized under the CLSD program.

(f) *Cooperation with National Evaluation.*

Grantees must cooperate with a national evaluation of the CLSD program (34 CFR 75.591). The evaluation will include high-quality research that applies rigorous and systematic procedures to obtain valid knowledge relevant to the implementation and effect of the CLSD program. The evaluation will directly coordinate with individual State evaluations of the CLSD program implementation.

Definitions: The definitions of ''comprehensive literacy instruction,'' ''eligible entity,'' and ''high-need school'' are from section 2221 of the ESEA. Except as otherwise specified, the definitions of ''child with a disability,'' ''English learner,'' ''evidence-based,'' ''multi-tier system of supports,'' ''poverty line,'' ''professional development,'' ''school leader,'' and ''well-rounded education'' are from section 8101 of the ESEA. The definitions of ''disconnected youth,'' ''early learning,'' ''educator,'' ''military- or veteran-connected student,'' and ''underserved student'' are from, and apply to, the Supplemental Priorities.

Child with a disability has the meaning given to the term in section 602 of the Individuals with Disabilities Education Act.

Comprehensive literacy instruction means instruction that-–

(a) Includes developmentally appropriate, contextually explicit, and systematic instruction, and frequent practice, in reading and writing across content areas;

(b) Includes age-appropriate, explicit, systematic, and intentional instruction in phonological awareness, phonic decoding, vocabulary, language structure, reading fluency, and reading comprehension;

(c) Includes age-appropriate, explicit instruction in writing, including opportunities for children to write with clear purposes, with critical reasoning appropriate to the topic and purpose, and with specific instruction and feedback from instructional staff;

(d) Makes available and uses diverse, high-quality print materials that reflect the reading and development levels, and interests, of children;

(e) Uses differentiated instructional approaches, including individual and small group instruction and discussion;

(f) Provides opportunities for children to use language with peers and adults in order to develop language skills, including developing vocabulary;

(g) Includes frequent practice of reading and writing strategies;

(h) Uses age-appropriate, valid, and reliable screening assessments, diagnostic assessments, formative assessment processes, and summative assessments to identify a child's learning needs, to inform instruction, and to monitor the child's progress and the effects of instruction;

(i) Uses strategies to enhance children's motivation to read and write and children's engagement in self-directed learning;

(j) Incorporates the principles of universal design for learning;

(k) Depends on teachers' collaboration in planning, instruction, and assessing a child's progress and on continuous professional learning; and

(l) Links literacy instruction to the challenging State academic standards, including the ability to navigate, understand, and write about complex print and digital subject matter.

Disconnected youth means an individual, between the ages 14 and 24,[6] who may be from a low-income background, experiences homelessness, is in foster care, is involved in the justice system, or is not working or not enrolled in (or at risk of dropping out of) an educational institution.

Early learning means any (a) State-licensed or State-regulated program or provider, regardless of setting or funding source, that provides early care and education for children from birth to kindergarten entry, including, but not limited to, any program operated by a child care center or in a family child care home; (b) program funded by the Federal Government or State or local educational agencies (including any IDEA-funded program); (c) Early Head Start and Head Start program; (d) non-relative child care provider who is not otherwise regulated by the State and who regularly cares for two or more unrelated children for a fee in a provider setting; and (e) other program that may deliver early learning and development services in a child's home, such as the Maternal, Infant, and Early Childhood Home Visiting Program; Early Head Start; and Part C of IDEA.

Educator means an individual who is an early learning educator, teacher, principal or other school leader, specialized instructional support personnel (*e.g.,* school psychologist, counselor, school social worker, early intervention service personnel), paraprofessional, or faculty.

Eligible entity means an entity that consists of—

(a) One or more LEAs that serve a high percentage of high-need schools and—

(1) Have the highest number or proportion of children who are counted under section 1124(c) of the ESEA, in comparison to other LEAs in the State;

(2) Are among the LEAs in the State with the highest number or percentages of children reading or writing below grade level, based on the most currently available State academic assessment data under section 1111(b)(2) of the ESEA; or

(3) Serve a significant number or percentage of schools that are implementing comprehensive support and improvement activities and targeted support and improvement activities under section 1111(d) of the ESEA;

(b) One or more early childhood education programs serving low-income or otherwise disadvantaged children, which may include home-based literacy programs for pre-school-aged children, that have a demonstrated record of providing comprehensive literacy instruction for the age group such program proposes to serve; or

(c) An LEA, described in paragraph (a), or consortium of such LEAs, or an early childhood education program, which may include home-based literacy programs for preschool-aged children, acting in partnership with one or more public or private nonprofit organizations or agencies (which may include early childhood education programs) that have a demonstrated record of effectiveness in—

(1) Improving literacy achievement of children, consistent with the purposes of participation under the CLSD program, from birth through grade 12; and

(2) Providing professional development in comprehensive literacy instruction.

English learner means an individual—

(a) Who is aged 3 through 21;

(b) Who is enrolled or preparing to enroll in an elementary school or secondary school;

(c)(i) Who was not born in the United States or whose native language is a language other than English;

(ii)(I) Who is a Native American or Alaska Native, or a native resident of the outlying areas; and (II) Who comes from an environment where a language other than English has had a significant impact on the individual's level of English language proficiency; or

(iii) Who is migratory, whose native language is a language other than English, and who comes from an environment where a language other than English is dominant; and

(d) Whose difficulties in speaking, reading, writing, or understanding the English language may be sufficient to deny the individual—

(i) The ability to meet the challenging State academic standards;

(ii) The ability to successfully achieve in classrooms where the language of instruction is English; or

(iii) The opportunity to participate fully in society.

Evidence-based, when used with respect to a State, LEA, or school activity, means an activity, strategy, or intervention that demonstrates a statistically significant effect on improving student outcomes or other relevant outcomes based on—

(a) Strong evidence from at least one well designed and well-implemented experimental study;

(b) Moderate evidence from at least one well-designed and well-implemented quasi-experimental study; or

(c) Promising evidence from at least one well-designed and well-implemented correlational study with statistical controls for selection bias.

High-need school means—

(a)(i) An elementary school or middle school in which not less than 50 percent of the enrolled students are children from low-income families; or

(ii) A high school in which not less than 40 percent of the enrolled students are children from low-income families, which may be calculated using comparable data from the schools that feed into the high school.

[6] CLSD serves youth from birth to grade 12. To the extent that State laws include youth up to age 24 in grade 12, those students may be served.

(b) For the purposes of paragraph (a) of this definition, the term ''low-income family'' means a family—

(i) In which the children are eligible for a free or reduced-price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 *et seq.*);

(ii) Receiving assistance under the program of block grants to States for temporary assistance for needy families established under part A of title IV of the Social Security Act (42 U.S.C. 601 *et seq.*); or

(iii) In which the children are eligible to receive medical assistance under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 *et seq.*).

Military- or veteran-connected student means one or more of the following:

(a) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a member of the uniformed services (as defined by 37 U.S.C. 101), in the Army, Navy, Air Force, Marine Corps, Coast Guard, Space Force, National Guard, Reserves, National Oceanic and Atmospheric Administration, or Public Health Service or is a veteran of the uniformed services with an honorable discharge (as defined by 38 U.S.C. 3311).

(b) A student who is a member of the uniformed services, a veteran of the uniformed services, or the spouse of a service member or veteran.

(c) A child participating in an early learning program, a student enrolled in preschool through grade 12, or a student enrolled in career and technical education or postsecondary education who has a parent or guardian who is a veteran of the uniformed services (as defined by 37 U.S.C. 101).

Multi-tier system of supports means a comprehensive continuum of evidence-based, systemic practices to support a rapid response to students' needs, with regular observation to facilitate data-based instructional decisionmaking.

Poverty line means the poverty line (as defined by the Office of Management and Budget and revised annually in accordance with section 673(2) of the Community Services Block Grant Act) applicable to a family of the size involved.

Professional development means activities that—

(a) Are an integral part of school and LEA strategies for providing educators (including teachers, principals, other school leaders, specialized instructional support personnel, paraprofessionals, and as applicable, early childhood educators) with the knowledge and skills necessary to enable students to succeed in a well-rounded education and to meet the challenging State academic standards; and

(b) Are sustained (not stand-alone, one-day, or short-term workshops), intensive, collaborative, job-embedded, data-driven, and classroom-focused, and may include activities that—

(1) Improve and increase teachers'—

(i) Knowledge of the academic subjects the teachers teach;

(ii) Understanding of how students learn; and

(iii) Ability to analyze student work and achievement from multiple sources, including how to adjust instructional strategies, assessments, and materials based on such analysis;

(2) Are an integral part of broad schoolwide and districtwide educational improvement plans;

(3) Allow personalized plans for each educator to address the educator's specific needs identified in observation or other feedback;

(4) Improve classroom management skills;

(5) Support the recruitment, hiring, and training of effective teachers, including teachers who became certified through State and local alternative routes to certification;

(6) Advance teacher understanding of—

(i) Effective instructional strategies that are evidence-based; and

(ii) Strategies for improving student academic achievement or substantially increasing the knowledge and teaching skills of teachers;

(7) Are aligned with, and directly related to, academic goals of the school or LEA;

(8) Are developed with extensive participation of teachers, principals, other school leaders, parents, representatives of Indian tribes (as applicable), and administrators of schools to be served under this program;

(9) Are designed to give teachers of English learners, and other teachers and instructional staff, the knowledge and skills to provide instruction and appropriate language and academic support services to those children, including the appropriate use of curricula and assessments;

(10) To the extent appropriate, provide training for teachers, principals, and other school and community-based early childhood program leaders in the use of technology (including education about the harms of copyright piracy), so that technology and technology applications are effectively used in the classroom to improve teaching and learning in the curricula and academic subjects in which the teachers teach;

(11) As a whole, are regularly evaluated for their impact on teacher effectiveness and student academic achievement, with the findings of the evaluations used to improve the quality of professional development;

(12) Are designed to give teachers of children with disabilities or children with developmental delays, and other teachers and instructional staff, the knowledge and skills to provide instruction and academic support services to those children, including positive behavioral interventions and supports, multi-tier system of supports, and use of accommodations;

(13) Include instruction in the use of data and assessments to inform classroom practice;

(14) Include instruction in ways that teachers, principals, other school leaders, specialized instructional support personnel, and school administrators may work more effectively with parents and families;

(15) Involve the forming of partnerships with institutions of higher education, including, as applicable, Tribal Colleges and Universities as defined in section 316(b) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1059c(b)), to establish school-based teacher, principal, and other school leader training programs that provide prospective teachers, novice teachers, principals, and other school leaders with an opportunity to work under the guidance of experienced teachers, principals, other school leaders, and faculty of such institutions;

(16) Create programs to enable paraprofessionals (assisting teachers employed by an LEA receiving assistance under part A of title I of the ESEA) to obtain the education necessary for those paraprofessionals to become certified and licensed teachers;

(17) Provide follow-up training to teachers who have participated in activities described in this paragraph that are designed to ensure that the knowledge and skills learned by the teachers are implemented in the classroom; and

(18) Where practicable, provide jointly for school staff and other early childhood education program providers, to address the transition to elementary school, including issues related to school readiness.

School leader means a principal, assistant principal, or other individual who is—

(a) An employee or officer of an elementary school or secondary school, LEA, or other entity operating an elementary school or secondary school; and

(b) Responsible for the daily instructional leadership and managerial operations in the elementary school or secondary school building.

Underserved student means a student (which may include children in early learning environments and students in K–12 programs, as appropriate) in one or more of the following subgroups:

(a) A student who is living in poverty or is served by schools with high concentrations of students living in poverty.

(b) A student of color.

(c) A student who is a member of a federally recognized Indian Tribe.

(d) An English learner.

(e) A child or student with a disability.

(f) A disconnected youth.

(g) A migrant student.

(h) A student experiencing homelessness or housing insecurity.

(i) A student who is in foster care.

(j) A student without documentation of immigration status.

(k) A pregnant, parenting, or caregiving student.

(l) A student impacted by the justice system, including a formerly incarcerated student.

(m) A student performing significantly below grade level.

(n) A military- or veteran- connected student. For the purpose of this definition only—

Children or students with disabilities means children with disabilities as defined in section 602(3) of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1401(3)) and 34 CFR 300.8, or students with disabilities, as defined in the Rehabilitation Act of 1973 (29 U.S.C. 705(37), 705(202)(B)).

English learner means an individual who is an English learner as defined in section 8101(20) of the Elementary and Secondary Education Act of 1965, as amended, or an individual who is an English language learner as defined in section 203(7) of the Workforce Innovation and Opportunity Act.

Well-rounded education means courses, activities, and programming in subjects such as English, reading or language arts, writing, science, technology, engineering, mathematics, foreign languages, civics and government, economics, arts, history, geography, computer science, music, career and technical education, health, physical education, and any other subject, as determined by the State or LEA, with the purpose of providing all students access to an enriched curriculum and educational experience.

Program Authority: Sections 2221–2225 and 2301 of the ESEA.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The Supplemental Priorities.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $185,000,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2025 from the list of unfunded applications from this competition.

Estimated Range of Awards (Annual): $9,500,000–$12,000,000.

Estimated Average Size of Awards (Annual): $11,000,000.

Estimated Number of Awards: 15–20.

Note: The Department is not bound by any estimates in this notice.

Project Period: 60 months. The Secretary may renew a grant for an additional two-year period upon the termination of the initial grant period if the grant recipient demonstrates to the satisfaction of the Secretary that (1) the State has made adequate progress; and (2) renewing the grant for an additional two-year period is necessary to carry out the objectives of the grant detailed in section 2222(d) of the ESEA.

III. Eligibility Information

1. *Eligible Applicants:* SEAs of the 50 States, the District of Columbia, and Puerto Rico (also referred to in this notice as States).

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements. Section 2301 of the ESEA provides that funds made available under this program must be used to supplement, and not supplant, non-Federal funds that would otherwise be used for CLSD program activities by grantees and subgrantees.

c. *Indirect Cost Rate Information:* This program uses a restricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c), a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to eligible entities.

The grantee must award subgrants to entities it selects through a competition under procedures established by the grantee and consistent with sections 2222–2224 of the ESEA.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application.

2. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the CLSD program, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application,

under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

4. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, resumes, bibliography, logic model, or letters of support. However, the recommended page limit does apply to all of the application narrative.

6. *Notice of Intent to Apply:* The Department will be able to review grant applications more efficiently if we know the approximate number of applicants that intend to apply. Therefore, we strongly encourage each potential applicant to notify us of their intent to submit an application. To do so, please email the program contact person listed under **FOR FURTHER INFORMATION CONTACT** with the subject line ''Intent to Apply,'' and include the applicant's name and a contact person's name and email address. Applicants that do not submit a notice of intent to apply may still apply for funding; applicants that do submit a notice of intent to apply are not bound to apply or bound by the information provided.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210. The maximum possible score for addressing all criteria is 100 points. The maximum possible score for addressing each criterion is indicated in parentheses. The selection criteria for this competition are as follows:

(a) *Need for project* (0 to 5 points).

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers the extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(b) *Quality of the project design* (0 to 30 points).

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (10 points)

(2) The extent to which the design of the proposed project includes a thorough, high-quality review of the relevant literature, a high-quality plan for project implementation, and the use of appropriate methodological tools to ensure successful achievement of project objectives. (10 points).

(3) The extent to which the proposed project is supported by promising evidence (as defined in 34 CFR 77.1(c)). (10 points).

(c) *Quality of management plan* (0 to 40 points).

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (10 points).

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (10 points).

(3) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project. (10 points).

(4) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project. *Note:* Applicants may consider subrecipient monitoring as an example of a mechanism in addressing this sub-criterion. (10 points).

(d) *Quality of project services* (0 to 15 points).

The Secretary considers the quality of the project services to be provided by the proposed project. In determining the quality of project services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. In addition, the Secretary considers:

(1) The likely impact of the services to be provided by the proposed project on the intended recipients of those services; (5 points) and

(2) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services. (5 points).

(3) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice. (5 points).

(e) *Quality of project evaluation* (0 to 10 points).

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (5 points).

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes. (5 points).

2. *Review and Selection Process:* We remind potential applicants that, in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

5. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We also may notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* For purposes of Department reporting under 34 CFR 75.110, the Department has established the following performance measures for the CLSD program:

(1) The percentage of participating four-year-old children who achieve significant gains in oral language skills, as determined by a State-approved measure.

(2) The percentage of participating fifth-grade students who meet or exceed proficiency on State reading/language arts assessments under section 1111(b)(2)(B)(v)(I) of the ESEA.

(3) The percentage of participating eighth-grade students who meet or exceed proficiency on State reading/language arts assessments under section 1111(b)(2)(B)(v)(I) of the ESEA.

(4) The percentage of participating high school students who meet or exceed proficiency on State reading/language arts assessments under section 1111(b)(2)(B)(v)(I) of the ESEA.

All grantees will be expected to submit an annual performance report that includes data addressing these performance measures to the extent that they apply to the grantee's project. Performance targets will be established by each grantee and must be made for each year of the performance period, not to exceed five years.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project;

whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

7. *Annual Project Directors' Meetings:* Applicants approved for funding under this competition must attend a meeting for project directors at a location to be determined in the continental United States during each year of the project. Applicants may include, if applicable, the cost of attending this meeting in their proposed budgets as allowable administrative costs.

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Adam Schott,

Principal Deputy Assistant Secretary, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2024–08578 Filed 4–22–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0060]

Agency Information Collection Activities; Comment Request; Regional Educational Laboratory (REL) Southwest Effective Advising Framework Evaluation

AGENCY: Institute of Education Sciences (IES), 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 June 24, 2024.

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–2024–SCC–0060. 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 Anousheh Shayestehpour, (202)–987–1148.

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: Regional Educational Laboratory (REL) Southwest Effective Advising Framework Evaluation.

OMB Control Number: 1850–NEW.

Type of Review: New ICR.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 2,153.

Total Estimated Number of Annual Burden Hours: 611.

Abstract: By 2030, the Texas Higher Education Coordinating Board expects that 60 percent or more of all new jobs in Texas will require some postsecondary education. However, in 2019, less than half of the Texas population ages 25–34 years (44.3 percent) had some type of postsecondary credential. To close this gap and support districts in meeting the state statute that requires schools to fully develop each student's academic, career, personal, and social abilities, the Counseling, Advising, and Student Supports team (under the Division of College, Career, and Military Preparation) at the Texas Education Agency established the Effective Advising Framework. This framework expands access to effective college and career advising by streamlining and modernizing advising offerings and

services for secondary and postsecondary students. The initiative aims to support students in making informed decisions about postsecondary education and careers and to offer professional development to educators and guidance counselors on advising services.

This proposed study will examine the implementation of the Effective Advising Framework across school districts participating in the pilot program. Because it is expected that districts are applying the framework in a variety of ways, the study will examine the variation in implementation across districts, including an analysis of the factors that support or hinder implementation. To do this, the research team will collect data from public education staff at the school, district, and regional levels. Surveys will be administered to gather information on how and what is being implemented at each level and what factors may act as barriers to successful implementation. One-on-one interviews and focus group interviews will be conducted with a subsample of respondents from each level to gather more in-depth information on the successes and challenges they faced in applying the framework. The results of this study will inform the continued development of the framework and the associated resources and supports that will be provided to districts and schools when the initiative is implemented statewide.

Dated: April 17, 2024.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–08584 Filed 4–22–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–348–D]

Application for Renewal of Authorization To Export Electric Energy; NextEra Energy Marketing, LLC

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: NextEra Energy Marketing, LLC (Applicant or NEM) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before May 23, 2024.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Janessa Zucchetto, (240) 474–8226, *Electricity.Exports@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On February 11, 2009, DOE issued Order No. EA–348 to FPL Energy Power Marketing, Inc. to transmit electric energy from the United States to Canada as a power marketer for a period of five years. This authority was amended in March 2009 to effectuate a name change to NextEra Energy Power Marketing, LLC (Order No. EA–348–A). This authority was renewed in 2014 (Order No. EA–348–B) and 2019 (Order No. EA–348–C). On March 21, 2024, NEM filed an application with DOE (Application or App.) for renewal of its export authority for a five-year term. App. at 1.

According to the Application, NEM is a Delaware corporation that is a wholly owned direct subsidiary of NextEra Energy Resources, LLC. App. at 1–2. NEM states it does not own any transmission facilities. *Id.* at 2. NEM further states that its affiliate, NextBridge Infrastructure LP, owns and operates the East-West Tie transmission project in Ontario, Canada, including 280 miles of double-circuit 230 kV line. *Id.* at 2–3. The Applicant represents that the electricity it proposes to export will be purchased from others voluntarily and will, therefore, be surplus to the needs of the selling entities. *Id.* at 3. NEM also states it will comply with applicable reliability standards, export limits, and general conditions set by DOE. *Id.* at 4. NEM asserts its proposed exports will not impair or impede sufficient electric supplies in the United States or the regional coordination of electric utility planning or operations. *Id.* at 3.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at *Electricity.Exports@hq.doe.gov.* Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at *Electricity.Exports@hq.doe.gov* in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning NEM's Application should be clearly marked with GDO Docket No. EA–348–D. Additional copies are to be provided directly to William Lavarco, NextEra Energy Resources, LLC, 801 Pennsylvania Ave. NW, Suite 220, Washington, DC 20004, *william.lavarco@nee.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *https://www.energy.gov/gdo/pending-applications-0* or by emailing *Electricity.Exports@hq.doe.gov.*

Signing Authority: This document of the Department of Energy was signed on April 16, 2024, by Maria Robinson, Director, Grid Deployment Office, 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 April 17, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–08562 Filed 4–22–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, May 16, 2024; 5:30–7:00 p.m. CDT.

ADDRESSES: West Kentucky Community and Technical College, Emerging Technology Center, Room 215, 5100 Alben Barkley Drive, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: Robert ''Buz'' Smith, Federal Coordinator, by Phone: (270) 441–6821 or Email: *Robert.Smith@pppo.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda:

- Administrative Activities.
- Public Comment Period.

Public Participation: The meeting is open to the public. The EM SSAB, Paducah will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Robert ''Buz'' Smith in advance of the meeting. The EM SSAB, Paducah will hear oral public comments during the meeting. Written statements may be filed either before or after the meeting. Written comments received by no later than 5 p.m. CDT on Monday, May 13, 2024, will be read aloud during the meeting. Written comments submitted by 5 p.m. CDT on Friday, May 24, 2024, will be included in the minutes. Please submit written comments to Robert ''Buz'' Smith with ''Public Comment'' in the subject line. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: Minutes will be available by writing or calling Eric Roberts, Board Support Manager, Emerging Technology Center, Room 221, 4810 Alben Barkley Drive, Paducah, KY 42001; Phone: (270) 554–3004. Minutes will also be available at the following website: *https://www.energy.gov/pppo/pgdp-cab/listings/meeting-materials.*

Signing Authority: This document of the Department of Energy was signed on April 18, 2024, by David Borak, Deputy Committee Management Officer, 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 April 18, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–08662 Filed 4–22–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–312–C]

Application for Renewal of Authorization To Export Electric Energy; Emera Energy U.S. Subsidiary No. 2, Inc.

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: Emera Energy U.S. Subsidiary No. 2, Inc. (the Applicant or EE US No. 2) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before May 23, 2024.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Janessa Zucchetto, (240) 474–8226, *electricity.exports@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) under Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On May 17, 2006, DOE issued Order No. EA–312, authorizing EE US No. 2 to transmit electric energy from the United States to Canada as a power marketer. This authority was renewed in 2014 (Order No. EA–312–A), and 2019 (Order No. EA–312–B). On March 22, 2024, EE US No. 2 filed an application with DOE (Application or App) for renewal of its export authority for an additional five-year term. App at 1.

In its Application, EE US No. 2 states it is a Delaware corporation with its principal place of business in Kittery, Maine, and a wholly-owned subsidiary of Emera Incorporated. App. at 1. The Applicant states that it ''does not own or control any electric power generation or transmission facilities and does not have a franchised electric power service area. EE US No. 2 operates as a marketing company involved in, among other things, the purchase and sale of electricity in the United States as a power marketer.'' *Id.* at 6. EE US No. 2 represents that it ''will purchase surplus electric energy from electric utilities and other suppliers within the United States and will export this energy to Canada over the international electric transmission facilities.'' *Id.* at 7. Therefore, the Applicant contends that ''[b]ecause this electric energy will be

purchased from others voluntarily, it will be surplus to the needs of the selling entities. EE US No. 2's export of power will not impair the sufficiency of electric power supply in the U.S.'' *Id.* Further, the Applicant asserts its exports will comply with all applicable requirements and export limits imposed by DOE and therefore ''will not impede or tend to impede the coordinated use of transmission facilities within the meaning of Section 202(e) of the FPA.'' *Id.* at 8.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the email address provided previously. Protests should be filed in accordance with Rule 211 of FERC's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the previously provided email address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning EE US No. 2's Application should be clearly marked with GDO Docket No. EA–312–C. Additional copies are to be provided directly to Keith Sutherland, Emera Energy Inc., 5151 Terminal Road, Halifax, NS B3J 1A1 Canada, *keith.sutherland@emeraenergy.com,* Jeffery M. Jakubiak, Vinson & Elkins LLP, 1114 Avenue of the Americas, 32nd Floor, New York, NY 10036, *JJakubiak@velaw.com,* and Jennifer C. Mansh, Vinson & Elkins LLP, 2200 Pennsylvania Ave, NW, Suite 500 West, Washington, DC 20037, *Jmansh@velaw.com.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *https://www.energy.gov/gdo/pending-applications-0* or by emailing *Electricity.Exports@hq.doe.gov.*

Signing Authority: This document of the Department of Energy was signed on April 16, 2024, by Maria Robinson, Director, Grid Deployment Office, 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 April 17, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–08563 Filed 4–22–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1770–000]

AMA QSE, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of AMA QSE, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 7, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: April 17, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08621 Filed 4–22–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC24–7–000]

Commission Information Collection Activities (FERC–512) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–512 (Preliminary Permit). The 60-day notice comment period ends on April 8, 2024, no comments were received.

DATES: Comments on the collection of information are due May 23, 2024.

ADDRESSES: Send written comments on FERC–512 to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory

Commission Desk Officer. Please identify the OMB Control Number (1902–0073) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC24–07–000) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by other delivery methods:

○ *Mail via U.S. Postal Service Only:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *All other delivery methods:* Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov/ferc-online/overview.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *https://www.ferc.gov/ferc-online/overview.*

FOR FURTHER INFORMATION CONTACT: Jean Sonneman may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–6362.

SUPPLEMENTARY INFORMATION:

Title: FERC–512, Preliminary Permit.

OMB Control No.: 1902–0073.

Type of Request: Three-year approval of the FERC–512 information collection requirements, with no changes to the current reporting requirements.

Abstract: Sections 4(f) and 5(b) of the Federal Power Act authorize the Commission to issue a preliminary permit for a term of up to four years, extend a permit term once for not more than four additional years, and issue an additional permit after the end of an extension period.[1] The FERC–512 is an application for a preliminary permit or to extend a preliminary permit term. The purpose of obtaining a preliminary permit is to maintain priority status for an application for a license while the applicant conducts site examinations and surveys to inform a decision on whether to pursue a license for the project, and if so, prepare a license application. A preliminary permit neither authorizes construction of any facilities, nor provides the use of eminent domain to acquire lands for the project. No application for a preliminary permit or license submitted by another party can be accepted during the permit term.

Commission staff review preliminary permit applications to assess the scope of the proposed project, the technology to be used, and jurisdictional aspects of the project. The staff assessment includes a review of the proposed hydro development for conflicts with other current permits or licensed projects, and issuance of public notice of the permit application to solicit public and agency comments. An application for a preliminary permit includes the applicant's name and contact information, a description of the proposed project, the requested term of the permit, names and addresses of the affected political jurisdictions, a verification of the application's facts, and three exhibits, per 18 CFR 4.81.

Type of Respondents: Business or other for-profit and not-for-profit entities.

Estimate of Annual Burden[2] *and Cost:*[3] The Commission estimates as shown below in the table:

FERC–512: (PRELIMINARY PERMIT)

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hours & cost per response	Total annual burden hours & total annual cost	Average annual cost per respondent
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Annual Reporting and Recordkeeping	65	1	65	24 hrs.; $2,400	1,560 hrs.; $156,000	$2,400
TOTAL FERC–512	65	1	65	24 hrs.; $2,400	1,560 hrs.; $156,000	2,400

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: April 17, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08626 Filed 4–22–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 16 U.S.C. 802 and 16 U.S.C. 798(b)(1).

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

[3] Commission staff estimates that the industry's skill set and cost (for wages and benefits) for FERC–512 are approximately the same as the Commission's average cost. The FERC 2024 average salary plus benefits for one FERC full-time equivalent (FTE) is $207,787/year (or $100/hour).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meetings

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: April 25, 2024, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: Agenda.

* Note: Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Debbie-Anne A. Reese, Acting Secretary, Telephone (202) 502–8400.

For a recorded message listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed online at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

1112TH—MEETING

[Open meeting—April 25, 2024, 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A-1	AD24–1–000	Agency Administrative Matters.
A-2	AD24–2–000	Customer Matters, Reliability, Security and Market Operations.
A–3	AD24–8–000	FERC, NERC, and Regional Entity Presentation into the January 2024 Arctic Storms.
	Electric	
E-1	ER24–340–001	Midcontinent Independent System Operator, Inc.
E–2	ER24–1225–000	California Independent System Operator Corporation.
E-3	ER24–1295–000	Moscow Development Company, LLC.
E–4	OMITTED.	
E–5	RM05–5–031	Standards for Business Practices and Communication Protocols for Public Utilities.
	Gas	
G–1	RP18–75–008	Algonquin Gas Transmission, LLC.
	Hydro	
H–1	P–943–146	Public Utility District No. 1 of Chelan County, Washington.
H–2	P–15318–000	Cabin Run Pumped Storage, LLC.
H–3	P–15024–000	Pumped Hydro Storage LLC.
	Certificates	
C–1	CP23–546–000	El Paso Natural Gas Company, L.L.C.
C–2	CP23–492–000	Florida Gas Transmission Company, LLC.
C–3	CP23–539–000	Cove Point LNG, LP.
C–4	CP19–14–003	Mountain Valley Pipeline, LLC.
C–5	CP23–466–000	Great Basin Gas Transmission Company.

A free webcast of this event is available through the Commission's website. Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The Federal Energy Regulatory Commission provides technical support for the free webcasts. Please call (202) 502–8680 or email *customer@ferc.gov* if you have any questions.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters but will not be telecast.

Issued: April 18, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08783 Filed 4–19–24; 4:15 pm]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

FEDERAL ENERGY REGULATORY COMMISSION

Sunshine Act Meetings

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: May 13, 2024, 11:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: Agenda.

* *Note:* Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Debbie-Anne A. Reese, Acting Secretary, Telephone (202) 502–8400.

For a recorded message listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed online at the Commission's website at *https://elibrary.ferc.gov/eLibrary/search* using the eLibrary link.

1113TH—MEETING

[Open meeting, May 13, 2024, 11:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD24–1–000	Agency Administrative Matters.
A–2	AD24–2–000	Customer Matters, Reliability, Security and Market Operations.
	Electric	
E–1	RM21–17–000	Building for the Future Through Electric Regional Transmission Planning and Cost Allocation.
E–2	RM22–7–000	Applications for Permits to Site Interstate Electric Transmission Facilities.

A free webcast of this event is available through the Commission's website. Anyone with internet access who desires to view this event can do so by navigating to *www.ferc.gov*'s Calendar of Events and locating this event in the Calendar. The Federal Energy Regulatory Commission provides technical support for the free webcasts. Please call (202) 502–8680 or email *customer@ferc.gov* if you have any questions.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters but will not be telecast.

Issued: April 18, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08782 Filed 4–19–24; 4:15 pm]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1390–069]

Southern California Edison Company; Notice of Intent To File License Application, Filing of Pre-Application Document (PAD), Commencement of Pre-Filing Process, and Scoping; Request for Comments on the PAD and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Process.

b. *Project No.:* 1390–069.

c. *Dated Filed:* February 23, 2024.

d. *Submitted By:* Southern California Edison Company (SCE).

e. *Name of Project:* Lundy Hydroelectric Project (Lundy Project).

f. *Location:* The Lundy Project is located on Mill Creek, on the eastern slope of the Sierra Nevada, approximately 8 miles northwest of Lee Vining in Mono County, California. The existing FERC project boundary occupies Federal lands within the Inyo National Forest (Inyo NF), managed by the U.S. Forest Service (FS), and partly on Federal land managed by the Bureau of Land Management (BLM), Bishop Field Office. The remaining Lundy Project lands are owned by SCE except for a small parcel of land near the powerhouse owned by Mono County.

g. *Filed Pursuant to:* 18 CFR part 5 of the Commission's Regulations.

h. *Applicant Contact:* Matthew Woodhall Relicensing Project Lead, Southern California Edison Company, 2244 Walnut Grove Avenue, Rosemead, CA 91770; (602) 302–9596; *matthew.woodhall@sce.com*.

i. *FERC Contact:* Jessica Fefer at (202) 502–6631 or email at *jessica.fefer@ferc.gov.*

j. *Cooperating agencies:* Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. *With this notice, we are initiating informal consultation with:* (a) the U.S. Fish and Wildlife Service and/or the National Oceanic and Atmospheric Administration Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402 and (b) the State Historic Preservation Office, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating SCE as the Commission's non-Federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. SCE filed with the Commission a Pre-Application Document (PAD), including a proposed process plan and schedule, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD may be viewed on the Commission's website (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659.

You may register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to these or other pending projects. For assistance, contact FERC Online Support.

o. With this notice, we are soliciting comments on the PAD and Commission staff's Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from staff related to the merits of the potential application must be filed with the Commission.

The Commission strongly encourages electronic filing. Please file all documents using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Support at *FERCOnlineSupport@ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–1390–069.

All filings with the Commission must bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by June 24, 2024.[1]

p. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

q. The Commission's scoping process will help determine the required level of analysis and satisfy the National Environmental Policy Act (NEPA) scoping requirements, irrespective of whether the Commission prepares an environmental assessment or environmental impact statement.

Scoping Meetings

Commission staff will hold two scoping meetings for the project to receive input on the scope of the NEPA document. An evening meeting will be held at 6:00 p.m. on May 14, 2024, at the Lee Vining Community Center in Lee Vining, California, and will focus on receiving input from the public. A daytime meeting will be held at 2:00 p.m. on May 15, 2024, at the same location, and will focus on the concerns of resource agencies, non-governmental organizations (NGOs), and Indian Tribes. We invite all interested agencies, Indian Tribes, non-governmental organizations, and individuals to attend one or both meetings. The times and locations of these meetings are as follows:

Evening Scoping Meeting

Date: Tuesday, May 14, 2024
Time: 6:00 p.m. (PST)
Place: Lee Vining Community Center
Address: 296 Mattly Ave., Lee Vining, CA 93541
Phone: (760) 647–6009

Daytime Scoping Meeting

Date: Wednesday, May 15, 2024
Time: 2:00 p.m. (PST)
Place: Lee Vining Community Center
Address: 296 Mattly Ave., Lee Vining, CA 93541
Phone: (760) 647–6009

SD1, which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list and SCE's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

Environmental Site Review

The applicant and Commission staff will conduct an environmental site review of the project. All interested individuals, agencies, Tribes, and NGOs are invited to attend. All participants are responsible for their own transportation to/from the project and during the site visit. Participants must wear sturdy, closed-toe shoes, or boots. Please RSVP via email to *Matthew.Woodhall@sce.com* or notify Matthew Woodhall at (626) 302–9596 *on or before May 8, 2024,* if you plan to attend the environmental site review. The time and location of the environmental site review is as follows:

Lundy Project

Date: Wednesday, May 15, 2024
Time: 9:00 a.m. (PST)
Place: Lee Vining Community Center
Address: 296 Mattly Ave., Lee Vining, CA 93541

Participants must meet at the Lee Vining Community Center parking lot to begin promptly at 9:00 a.m. where participants will drive in personal vehicles together to the project. At the project, participants will see recreation site(s), Lundy Dam and the Lundy Powerhouse.

Meeting Objectives

At the scoping meetings, Commission staff will: (1) initiate scoping of the issues; (2) review and discuss existing conditions; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of Federal, State, and Tribal permitting and certification processes; and (5) discuss the potential of any Federal or State agency or Indian Tribe to act as a cooperating agency for development of an environmental document.

[1] The Commission's Rules of Practice and Procedure provide that if a filing deadline falls on a Saturday, Sunday, holiday, or other day when the Commission is closed for business, the filing deadline does not end until the close of business on the next business day. 18 CFR 385.2007(a)(2) (2022). Because the filing deadline falls on a Saturday (*i.e.,* June 22, 2024), the filing deadline is extended until the close of business on Monday, June 24, 2024.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and SD1 are included in item n of this document.

Meeting Procedures

Commission staff are moderating the scoping meetings. The meetings are recorded by an independent stenographer and become part of the formal record of the Commission proceeding on the project. Individuals, NGOs, Indian Tribes, and agencies with environmental expertise and concerns are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the NEPA document.

Dated: April 17, 2024.

Debbie-Anne Reese,

Acting Secretary.

[FR Doc. 2024–08625 Filed 4–22–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2020–0413; FRL–11604–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing ICR Collection and Request for Comment; Toxic Substances Control Act (TSCA) Section 8(b) Reporting and Requirements for TSCA Inventory Notifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): ''TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications,'' identified by EPA ICR No. 2565.04 and OMB Control No. 2070–0201. This ICR represents a renewal of an existing ICR that is currently approved through January 31, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before June 24, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0413, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Division (7602M), 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) 566–1206; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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 submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR does this action apply to?

Title: TSCA Section 8(b) Reporting Requirements for TSCA Inventory Notifications.

EPA ICR No.: 2565.04.

OMB Control No.: 2070–0201.

ICR status: This ICR is currently approved through January 31, 2025. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR addresses the reporting and recordkeeping requirements under TSCA section 8(b) that are associated with the TSCA Chemical Substance Inventory (TSCA Inventory), as codified in 40 CFR part 710. TSCA section 8(b) specifically requires that EPA compile and keep current a list of chemical substances manufactured or processed for commercial purposes in the United States. That mandate was amended in 2016 and TSCA section 8(b)(4) requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either ''active'' or ''inactive'' in U.S. commerce. The first TSCA Inventory with all chemical substances designated as ''active'' or ''inactive'' published in February 2019.

This ICR addresses the activities and burdens associated with the ongoing reporting (EPA Form No. 9600–06; Notice of Activity Form B), including the substantiation of CBI and related recordkeeping requirements in 40 CFR part 710, and accounts for estimates from the ICR titled ''Final Rule; Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Notice of Activity Form As)'' (OMB Control No. 2070–0210; EPA ICR No. 2594.03). EPA finalized the requirements for regulated entities to substantiate certain CBI claims made under the TSCA to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory, and the Agency's plan for reviewing certain CBI claims for specific chemical identities in

a final rule titled ''Procedures for Review of CBI Claims for the Identity of Chemicals in the TSCA Inventory'' (85 FR 13062, March 6, 2020 (FRL–10005–48)). The substantiation requirements describe the applicable procedures and provide instructions for regulated entities. The Agency's plan set out the review criteria and related procedures that EPA will use to complete the reviews within the five-year timeframe set in TSCA, and the ongoing reporting and recordkeeping activities are incorporated into this ICR.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 147 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected are those that manufacture (defined by statute to include import) or process chemical substances that are regulated under TSCA. The following North American Industrial Classification System (NAICS) codes have been provided to assist in determining whether this action might apply to certain entities:

- NAICS Code 325 Chemical Manufacturers; and
- NACIS Code 324 Petroleum and Coal Products.

Respondent's obligation to respond: Mandatory, per 40 CFR part 710 and TSCA section 8.

Frequency of response: On occasion.

Total estimated number of potential respondents: 57.

Total estimated average number of responses for each respondent: 1.5.

Total estimated annual respondent burden hours: 143.6 hours.

Total estimated annual respondent costs: $19,956.68, which includes $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 90 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects a reduction in the estimated number of chemicals reported in each submission, *i.e.,* from 18 to an average one chemical. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 18, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–08637 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2024–0180; FRL–11893–01–OGC]

Proposed Settlement Agreement, Clean Air Act Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or ''the Act''), the Environmental Protection Agency (''EPA'' or ''the Agency'') is providing notice of a proposed settlement agreement in *United States Steel Corp.* v. *EPA,* Case Nos. 13–3595, 16–2668, and 18–1249 (8th Cir.). Petitioner United States Steel Corporation (''U.S. Steel'') has filed petitions for review in the United States District Court of Appeals for the Eighth Circuit, challenging final rules promulgated by EPA under the CAA related to regional haze best available retrofit technology determinations for taconite facilities owned and operated by U.S. Steel in Minnesota. The proposed settlement agreement would establish deadlines for EPA to take certain, specified actions.

DATES: Written comments on the proposed settlement agreement must be received by May 23, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0180 online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Settlement Agreement'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Grubb, Office of Regional Counsel, U.S. Environmental Protection Agency Region 5; telephone (312) 886–7187; email address *grubb.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Settlement Agreement

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2024–0180) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center 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 OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed settlement agreement, and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Settlement Agreement

In 2013, EPA issued a Regional Haze (RH) Federal Implementation Plan (FIP) that established nitrogen oxide (NO_X) and sulfur dioxide (SO_2) best available retrofit technology emission limits for U.S. Steel's Minntac and Keetac facilities. Approval and Promulgation of Air Quality Implementation Plans;

States of Minnesota and Michigan; Regional Haze State Implementation Plan; Federal Implementation Plan for Regional Haze. 78 FR 8706 (February 6, 2013) (Original FIP Rule). EPA has taken several subsequent actions to revise the Original FIP Rule and to address administrative petitions related to EPA's actions. U.S. Steel has filed multiple challenges in response to EPA's actions. U.S. Steel brought these challenges pursuant to sections 110, 169A, and 307 of the CAA, 42 U.S.C. 7410, 7491, and 7607. EPA reached a settlement with U.S. Steel for the Minntac facility in 2018.

The proposed settlement agreement (the ''Second Settlement Agreement'') relates to U.S. Steel's Keetac facility. The Second Settlement Agreement, if finalized, provides a process for resolving U.S. Steel's challenges in *United States Steel Corp.* v. *EPA,* Case Nos. 13–3595, 16–2668, and 18–1249 (8th Cir.). Under the Second Settlement Agreement, no later than twelve months after publication of notice of this settlement in the **Federal Register**, EPA would sign a proposed rulemaking proposing changes to the Original FIP Rule that is substantially consistent with, and contains numeric emission limits and time frames identical to those set forth in, Attachment A to the Second Settlement Agreement. If EPA timely signs a final rule that includes changes that are substantially consistent with, and includes numeric emission limits and time frames identical to those set forth in, Attachment A to the Second Settlement Agreement, and if no petition for review of the final rule has been filed in the U.S. Court of Appeals for the Eighth Circuit within sixty days, U.S. Steel will promptly file an appropriate pleading for the dismissal with prejudice of Case Nos. 13–3595, 16–2668, and 18–1249, which will resolve the litigation.

The proposed Second Settlement Agreement also includes standard language regarding resolution of costs and attorneys' fees, stipulation of extensions, lapses in appropriations, disputes in implementation, preservation of Agency discretion, and the CAA section 113(g) process.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed settlement agreement. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Settlement Agreement

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0180, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) 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/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2024–08613 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2020–0262; FRL–11605–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing ICR Collection and Request for Comment; Reporting and Recordkeeping for Asbestos Abatement Worker Protection

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): ''Reporting and Recordkeeping for Asbestos Abatement Worker Protection,'' identified by EPA ICR No. 1246.15 and OMB Control No. 2070–0072. This ICR represents a renewal of an existing ICR that is currently approved through January 31, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before June 24, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0262, through *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Divison (7602M), 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) 566–1206; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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 submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Information Collection Activity or ICR does this action apply to?

Title: Reporting and Recordkeeping for Asbestos Abatement Worker Protection.

EPA ICR No.: 1246.15.

OMB Control No.: 2070–0072.

ICR status: This ICR is currently approved through January 31. 2025. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This ICR covers reporting and recordkeeping requirements associated with EPA's workplace standards for the protection of state and local government employees who work with asbestos and who are not covered by a state plan approved by the Occupational Safety and Health Administration (OSHA). Currently, state and local government employees in 23 states, the District of Columbia (DC), and three additional U.S. territories (DC and the territories are counted as one ''state equivalent'') who perform construction work, including building construction, renovation, demolition, and maintenance activities, and employees who perform brake and clutch repair work, are covered by these requirements. EPA's asbestos worker protection regulations incorporate, by reference, the OSHA Construction Industry Standard for Asbestos (29 CFR 1926.1101) and the General Industry Standard for Asbestos (29 CFR 1910.1001). EPA requires state and local government employers to use engineering controls and appropriate work practices to control the release of asbestos fibers. Covered employers must also monitor employee exposure to asbestos and provide employees with personal protective equipment, training, and medical surveillance to reduce the risk of asbestos exposure. Exposure monitoring records must be maintained for 30 years, medical surveillance records for the duration of employment of the affected employees plus 30 years, and training records for the duration of employment plus one year. Employers must also establish written respiratory protection programs and maintain procedures and records of respirator fit tests for one year.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.32 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Respondents for this information collection include states and local government employers in the 23 states, DC, and the U.S. territories that have employees engaged in asbestos-related construction, custodial, and brake and clutch repair activities without OSHA-approved state plans. The following North American Industrial Classification System (NAICS) codes have been provided to assist in determining whether this action might apply to certain entities:

- Public Administration (NAICS Code 92), and
- Educational Services (NAICS Code 61.

Respondent's obligation to respond: Mandatory. 40 CFR 763.

Frequency of response: Occasional.

Total estimated number of potential respondents: 34,138.

Total estimated average number of responses for each respondent: 33.

Total estimated annual burden hours: 358,049 hours.

Total estimated annual costs: $19,960,188, which includes an estimated $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase in total burden costs of $3.066 million compared with that identified in the ICR currently approved by OMB, which reflects an increase of $10.45, or 23%, to the weighted average wage rate, and an increase of 10,701 in total respondents (state and local entities), reflecting updated numbers of governments from the Census of Governments. These increases are partially offset by a decrease of 46,824 in the total number of responses due to a decrease in the number of states subject to the rule compared with that identified in the ICR currently approved by OMB. There is a decrease in burden hours by 14,920 due to a decrease in estimated number of responses. These changes qualify as adjustments.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional

comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 18, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–08639 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2024–0179; FRL–11892–01–OGC]

Proposed Settlement Agreement, Clean Air Act Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or ''the Act''), the Environmental Protection Agency (''EPA'' or ''the Agency'') is providing notice of a proposed settlement agreement in *Cleveland-Cliffs, Inc.* v. *Environmental Protection Agency,* Case No. 16–2643 (8th Cir.) (and consolidated cases). Petitioners Cleveland-Cliffs, Inc. (Cliffs) and Cleveland-Cliffs Steel, LLC (Cliffs Steel) filed petitions for review in the United States Court of Appeals for the Eighth Circuit, challenging final rules promulgated by EPA under the CAA related to regional haze best available retrofit technology determinations for taconite facilities in Michigan and Minnesota. The proposed settlement agreement would establish deadlines for EPA to take certain, specified actions.

DATES: Written comments on the proposed settlement agreement must be received by May 23, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0179 online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Settlement Agreement'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Grubb, Office of Regional Counsel, U.S. Environmental Protection Agency Region 5; telephone (312) 886–7187; email address *grubb.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Settlement Agreement

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2024–0179) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center 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 OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed settlement agreement, and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Settlement Agreement

In February 2013, EPA issued a Regional Haze (RH) Federal Implementation Plan (FIP) that established nitrogen oxide (NO_x) and sulfur dioxide (SO_2) best available retrofit technology emission limits for taconite facilities in Minnesota and Michigan, entitled ''Approval and Promulgation of Air Quality Implementation Plans; States of Minnesota and Michigan; Regional Haze State Implementation Plan; Federal Implementation Plan for Regional Haze'' at 78 FR. 8706 (February 6, 2013) (the ''Original FIP Rule''). In September 2013, EPA issued partial disapprovals of Minnesota's and Michigan's regional haze SIPs for failure to require BART for the taconite furnaces, entitled ''Approval and Promulgation of Air Quality Implementation Plans; States of Michigan and Minnesota; Regional Haze,'' at 78 FR 59825 (September 30, 2013) (the ''SIP Rule''). Petitioners Cliffs and Cliffs Steel each filed a petition for review challenging the SIP Rule, and those petitions for review have been consolidated in the United States Court of Appeals for the Eighth Circuit under lead Case No. 13–3573. In 2016, EPA revised the Original FIP Rule to address administrative petitions related to EPA's actions, entitled ''Air Plan Approval; Minnesota and Michigan; Revision to 2013 Taconite Federal Implementation Plan Establishing BART for Taconite Plants; Final Rule,'' at 81 FR 21672 (April 12, 2016) (the ''Revised FIP Rule''). Petitioners Cliffs and Cliffs Steel each filed a petition for review challenging the Revised FIP Rule, and those petitions for review have been consolidated in the United States Court of Appeals for the Eighth Circuit under lead Case No. 16–2643.

The proposed settlement agreement, if finalized, provides a process for resolving all of Cliffs' and Cliffs Steel's challenges to the SIP Rule and the Revised FIP Rule. Under the proposed settlement agreement, no later than November 22, 2024, EPA would sign a proposed rulemaking proposing changes to the Revised FIP Rule that is substantially consistent with, and includes equations identical to those set forth in, Attachment A to the Settlement Agreement. If EPA timely signs a final rule that includes changes that are substantially consistent with, and includes equations identical to those set forth in, Attachment A to the Settlement Agreement, after the final rule has been published in the **Federal Register**, Cliffs and Cliffs Steel would promptly file an appropriate pleading for the dismissal with prejudice of Case Nos. 16–2643, 16–2653, 16–3446, 13–3573, 13–3575, and 14–1712, which will resolve the litigation.

The proposed Settlement Agreement also includes standard language regarding resolution of costs and attorneys' fees, stipulation of extensions, lapses in appropriations, disputes in implementation, preservation of Agency discretion, and the CAA section 113(g) process.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed settlement agreement. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is

inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Settlement Agreement

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0179, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) 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/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2024–08612 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11901–01–OA]

Local Government Advisory Committee (LGAC) and Small Communities Advisory Subcommittee (SCAS) Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), EPA herby provides notice of a meeting for the Local Government Advisory Committee (LGAC) and its Small Communities Advisory Subcommittee (SCAS) on the date and time described below. This meeting will be open to the public. For information on public attendance and participation, please see the registration information under **SUPPLEMENTARY INFORMATION**.

DATES: The SCAS will have a hybrid meeting prior to the LGAC on May 21st, 2024, from 8 a.m. to 9:30 a.m. eastern daylight time and the LGAC will have a hybrid meeting from 9:30 a.m. to 5 p.m. eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Paige Lieberman, Designated Federal Officer (DFO), at *LGAC@epa.gov* or 202–564–9957.

Information on Accessibility: For information on access or services for individuals requiring accessibility accommodations, please contact Paige Lieberman by email at *LGAC@epa.gov.* To request accommodation, please do so five (5) business days prior to the meeting, to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION:

Content

The LGAC will discuss several priority issues at EPA, including climate communication, environmental justice, and EPA's efforts to address cumulative impacts, and the reduction of plastic pollution. The SCAS will discuss a series of topics, including improving federal funding to smaller communities, and cyber security for small water systems. Agenda and meeting materials will be posted online (link below) one week prior to the meeting.

Registration

The meeting will be held virtually as well as in person. Members of the public who wish to participate should register by contacting the Designated Federal Officer (DFO) at *LGAC@epa.gov* by May 17, 2024.

Online participation will be via Microsoft Teams. In person participation will be Courtyard Marriott Hotel, 140 L St. SE, Washington, DC, 20003.

Once available, the agenda and other supportive meeting materials will be available online at *https://www.epa.gov/ocir/local-government-advisory-committee-lgac* and will be emailed to all registered. In the event of cancellation for unforeseen circumstances, please contact the DFO or check the website above for reschedule information.

Edlynzia Barnes,

Designated Federal Officer, Office of Congressional and Intergovernmental Relations.

[FR Doc. 2024–08643 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2024–0182; FRL–11897–01–OGC]

Proposed Consent Decree, Clean Air Act Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Our Children's Earth Foundation* v. *Michael Regan,* No. 1:23–cv–2848 (D.D.C.). On September 26, 2023, Plaintiff Our Children's Earth Foundation filed a complaint in the United States District Court for the District of Columbia. Plaintiff alleged that the Environmental Protection

Agency (EPA or the Agency) failed to perform certain non-discretionary duties in accordance with the Act to timely respond to numerous state implementation plan (SIP) submissions from the States of Alabama, Florida, Georgia, Louisiana, South Carolina, and Texas. The proposed consent decree would establish deadlines for EPA to act on certain submissions.

DATES: Written comments on the proposed consent decree must be received by May 23, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0182, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Kyle Durch, Air and Radiation Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone (202) 564–1809; email address *durch.kyle@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2024–0182) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center 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 OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

The proposed consent decree would establish deadlines for EPA to take action pursuant to CAA section 110(k) on certain SIP submissions by the States of Louisiana, South Carolina, and Texas. First, by June 30, 2025, EPA would sign a final rule to approve, conditionally approve, or disapprove, in whole or in part, five SIP revisions related to minor New Source Review permitting regulations which South Carolina submitted to EPA between October 2007 and July 2016.[1]

Second, EPA would sign a final rule to approve, conditionally approve, disapprove, in whole or in part, the following SIP submissions from Louisiana and Texas by September 30, 2025: LA 2010 SO_2 NAAQS transport prongs 1 and 2, submitted on or about June 7, 2013; TX Transport prongs 1 and 2 portion of the 2010 SO_2 Infrastructure & Transport SIP, submitted on or about May 9, 2013; six SIP revisions related to the 2008 Ozone Serious Area National Ambient Air Quality Standards for the Dallas-Fort Worth and Houston-Galveston-Brazoria nonattainment areas, including the Attainment Demonstrations, RACT Analyses, and RACT NO_X and VOC Rules for the Dallas-Fort Worth area, submitted on or about May 13, 2020; TX 30 TAC 101.118a2 and 101.118b from the Houston 1-hour ozone section 185 fee alternative program, submitted on or about November 30, 2018; and Revisions to Texas Chapter 116—Project Emissions Accounting, submitted on or about July 9, 2021.

Third, EPA would sign a final rule to approve, conditionally approve, disapprove, in whole or in part, TX 5-Year Regional Haze Progress Report SIP Revision, Texas Project 2013–013–SIP–NR, submitted March 20, 2014, submitted on or about March 24, 2014, no later than December 15, 2026.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0182, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) 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/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your

[1] The submissions identified from the States of Alabama, Florida, and Georgia, as well as certain submissions from the State of Texas, were acted upon by EPA, are part of other litigation, or withdrawn during the pendency of the suit and are thus no longer at issue. The remainder of this notice will focus only on the remaining submissions from the States of Louisiana, South Carolina, and Texas.

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2024–08614 Filed 4–22–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1126; FR ID 214934]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before May 23, 2024.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1126.

Title: Testing and Logging Requirements for Wireless Emergency Alerts (WEA).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 76 respondents, 429,020 responses.

Estimated Time per Response: 3.375 hours.

Frequency of Response: Monthly and on occasion reporting and record keeping requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection is contained in 47 U.S.C. 151, 152, 154, 301, 303, 307, 309, 316, 403, 554, 606, 1201, 1202, 1203, 1204, and 1206 of the Communications Act of 1934.

Total Annual Burden: 119,121 hours.

Total Annual Cost: No Cost.

Needs and Uses: The Commission adopted requirements for Participating CMS Providers to log the basic attributes of alerts they receive at their Alert Gateway, to maintain those logs for at least 12 months, to make those logs available upon request to the Commission and FEMA, and to emergency management agencies that offer confidentiality protection at least equal to that provided by federal FOIA. The Commission also requires Participating CMS Providers to disclose information regarding their capabilities for geo-targeting Alert Messages initiated by that emergency management agency, and information regarding the results of WEA Performance and Public Awareness Testing. These recordkeeping and reporting requirements have potential to increase emergency managers' confidence that WEA will work as intended when needed. This increased confidence in system availability encourages emergency management agencies that do not currently use WEA to become authorized. These reporting and recordkeeping requirements also help to ensure a fundamental component of system integrity against which future iterations of WEA can be evaluated. Without records that can be used to describe the quality of system integrity, and the most common causes of message transmission failure it would be difficult to evaluate how any changes to WEA may effect system integrity.

Federal Communications Commission.

Marlene Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2024–08623 Filed 4–22–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The 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 received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

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 May 23, 2024.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *Four States Bancshares, Inc., Carthage, Missouri;* to become a bank holding company by acquiring Four States Bank, Carthage, Missouri.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–08645 Filed 4–22–24; 8:45 am]

BILLING CODE 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 received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

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 May 8, 2024.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *comments.applications@phil.frb.org:*

1. *Castle Creek Capital Partners VIII, LP; Castle Creek Capital VIII LLC; Castle Creek Advisors VIII LLC; Castle Creek Special Situations II, LP; Castle Creek Special Situations II GP, LLC; Castle Creek Advisors IV LLC; JME Advisory Corp.; Scavuzzo Advisory Corp.; Volk Advisory Corp.; and Rana Advisory Corp., all of San Diego, California; John Eggemeyer, Rancho Santa Fe, California; Anthony Scavuzzo, Dallas, Texas; David Volk, San Diego, California; and Sundeep Rana, Dallas, Texas;* a group acting in concert, to acquire additional voting shares of Blue Ridge Bankshares, Inc., Richmond, Virginia, and thereby indirectly acquire additional voting shares of Blue Ridge Bank, National Association, Martinsville, Virginia.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–08644 Filed 4–22–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–24EP; Docket No. CDC–2024–0028]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled REACH: Rural Re-Engagement and Care using Community Health Workers (CHWs) for Persons with HIV. This project is designed to collect standardized program evaluation data from health departments and HIV clinic partners who receive Federal funds for these activities.

DATES: CDC must receive written comments on or before June 24, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0028 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) *or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

REACH: Rural Re-Engagement and Care using CHWs for Persons with HIV—New—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In rural communities, people with HIV (PWH) may face challenges in accessing consistent HIV care services. In these communities, PWH may also experience health care provider shortages and have fewer providers with expertise in treating HIV. Transportation challenges, where some patients have to travel long distances for care, may also exist. Previous studies have shown community-based or home-based delivery of care is an effective approach to re-engage PWH back into HIV clinical care. This strategy was studied primarily internationally with results showing that community-based delivery of anti-retroviral treatment (ART) significantly increased viral suppression. However, in the US, this model, which may include home visits, has not been implemented as part of routine treatment and care services. Community health workers (CHWs) are frontline public health workers who are trusted members of the community and have a uniquely close understanding of the community served. This trusting relationship enables the CHW to serve as a liaison between health/social services and the community. A CHW approach was assessed as part of the EHE pilot jumpstart initiative which found that CHWs were successful in East Baton Rouge, LA, by facilitating access to HIV treatment for priority populations. Additionally, the use of CHWs has been successful and cost-effective for certain chronic health conditions, particularly when working with low-income persons; people who are medically underserved, and racial/ethnic minority communities to promote disease management in these populations. This demonstration project will provide quantitative and qualitative data on the effectiveness and implementation of a CHW home-based approach to facilitate re-engagement in care and outreach to PWH. The approach aims to improve retention in care and sustained viral load suppression among PWH living in rural communities, to benefit both individual health and reduce community-level HIV transmission. In this demonstration project, recipients are funded to collaborate with HIV care providers to identify PWH in rural communities not in care or not virally suppressed and to implement a CHW-mediated model of re-engagement to care and outreach services for PWH in rural communities. CHWs facilitate re-engagement of PWH who are not in care and outreach to those who are not virally suppressed to provide services that may include ART delivery, sample collection for standard HIV laboratory testing, transfer of self-collected specimens, as well as provide transportation services, arranging and scheduling telehealth visits and/or in person visits with an HIV medical provider and other providers (mental health, primary care) and offer evidence-based medication adherence support.

This collection of deidentified data will allow CDC to assist health departments and their partner HIV clinics in monitoring and evaluating their programs and to identify best practices for provision of implementation of CHW-mediated services for re-engagement to care and outreach for PWH in rural communities. Longitudinal person-level data collection will occur through the clinic's electronic health record (EHR) and a database shared between clinic and the health department, and additional program evaluation data will be collected through client surveys. CDC requests approval for 295 annual burden hours for the recipients to collect, enter or upload, and report client demographic and behavioral characteristics, client data from the EHR, and client and provider surveys. There are no other costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
REACH Recipient Data Manager	Electronic Health Record Data Form	5	2	8	80
REACH Recipient Data Manager	Client Info Form	5	2	2	20
REACH Clients	Client Info Form	500	1	6/60	50
REACH Recipient/Clinic Staff	Client Info Form	5	100	6/60	50
REACH Recipient/Clinic Staff	Provider Info Form	5	10	6/60	5
REACH Clients	Client Program Evaluation Survey ...	100	1	42/60	70
REACH Recipient Data Manager	Client Program Evaluation Survey ...	5	2	2	20
Total	.....	.....	.....	.....	295

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08595 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–2024–24EO; Docket No. CDC–2024–0027]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Evaluation of HIV Self-Testing and Clinical Testing Guidelines Implementation. This project is designed to collect data from HIV healthcare providers, working in various settings, on the awareness and uptake of HIV-related guidelines.

DATES: CDC must receive written comments on or before June 24, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0027 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Evaluation of HIV Self-Testing and Clinical Testing Guidelines Implementation—New—National Centers for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It takes several years and a significant number of staff and resources to develop and disseminate guidelines. The Division of HIV Prevention (DHP) has been a leader in informing providers and program staff when it comes to HIV prevention through respective guidelines. Yet, DHP's understanding of the awareness and use of HIV-related guidelines has been limited. There have been few efforts and resources dedicated to assessing and evaluating guideline implementation. With DHP's impending completion and publication of the HIV self-testing and updated HIV testing guidelines in 2024, this project proposes a mixed methods approach to evaluate the awareness and uptake of these guidelines by providers using quantitative and qualitative methods. These providers include those who

work in health departments, community health centers, clinics, or community-based organizations.

The purpose of this data collection is to: (a) assess the awareness and use of the HIV self-testing and HIV testing guidelines by healthcare providers working in different health settings; (b) understand the barriers and facilitators to uptake of guidelines; and (c) inform CDC efforts to support guideline implementation through training, promotion, or technical assistance. The new HIV self-testing guideline and updated HIV testing guideline are yet to be published. This project is the first attempt to evaluate these guidelines and as such, no other Federal agency systematically collects this type of information from healthcare providers that supply HIV testing services. This data collection will allow DHP to understand how guidelines are being implemented in the early days of release and inform efforts including resource allocation for guideline development, translation, and implementation efforts.

CDC requests approval for a three-year information collection. Data are collected through surveys and virtual or phone interviews conducted with healthcare providers. There is no monetary compensation or incentives provided for participation in the interview or survey. These data may inform prevention program development and monitoring, resource allocation, and technical assistance needs at both the local and national levels. CDC estimates that this data collection will involve, 1100 surveys and 120 interviews in specific settings (community health centers, health departments, private clinics, public clinics, hospitals, and community-based organizations) over the course of three years. CDC requests OMB approval for an estimated 610 annual burden hours. Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Eligible Providers	Survey	1,100	1	30/60	550
Eligible Providers	Interview Questionnaire	120	1	30/60	60
Total					610

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08594 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–0666; Docket No. CDC–2024–0030]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Healthcare Safety Network (NHSN). NHSN provides facilities, States, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide.

DATES: CDC must receive written comments on or before June 24, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0030 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, Exp. 12/31/2026)—Revision—National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920–0666. NHSN provides facilities, States, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various healthcare-associated infection prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates. NHSN currently has eight components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis, Neonatal, and Medication Safety Component.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem. Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine: (1) the magnitude of adverse events in healthcare personnel; and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents. Under the Long-Term Care Facility Component, data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN. The Respiratory Tract Infection Form (RTI)—will not to be used by NHSN users, but as part of an EIP project with four EIP sites. The Form is titled Denominators for Healthcare Associated Infections (HAIs): Respiratory Tract Infections. The purpose of this form is to allow testing prior to introducing a new module and forms to NHSN users. The CDC's Epidemiology Research & Innovations Branch (ERIB) team will use the form to perform field testing of variables to explore the utilization, applicability, and data collection burden associated with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN. The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analysis processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities. The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs). The Neonatal Component focuses on premature neonates and the healthcare associated events that occur because of their prematurity. This component currently has one module, which includes Late Onset-Sepsis and Meningitis. The Medication Safety Component tracks medication safety and adverse drug events that are among the most common causes of iatrogenic harm in U.S. hospitals.

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the States. As of July 2023, 37 States, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those States and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes. NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the U.S. and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, State, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a Federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in States without HAI reporting legislation, submit limited HAI data to NHSN voluntarily. NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS' quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary

National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation.

The ICR was previously approved in March 2024 for 2,433,165 burden hours. The proposed changes in this new ICR include revisions to 80 existing data collection forms and three new forms. In this Revision, CDC requests OMB approval for an estimated annual burden 3,635,534 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (min./hour 60)	Total burden (hours)
57.100 NHSN Registration Form	2,000	1	5/60	167
57.101 Facility Contact Information	2,000	1	10/60	333
57.103 Patient Safety Component—Annual Hospital Survey	5,400	1	137/60	12,330
57.104 NHSN Facility Administrator Change Request Form	800	1	5/60	67
57.105 Group Contact Information	1,000	1	5/60	83
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60	23,463
57.108 Primary Bloodstream Infection (BSI)	6,000	12	30/60	36,000
57.111 Pneumonia (PNEU)	1,800	2	29/60	1,740
57.112 Ventilator-Associated Event (VAE)	5,463	8	28/60	20,395
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	31/60	173
57.114 Urinary Tract Infection (UTI)	6,000	12	20/60	24,000
57.115 Custom Event	600	91	35/60	31,850
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	240/60	52,800
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	300/60	30,000
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5,500	60	300/60	1,650,000
57.120 Surgical Site Infection (SSI)	3,800	12	11/60	8,360
57.121 Denominator for Procedure	3,800	12	11/60	8,360
57.122 HAI Progress Report State Health Department Survey	55	1	50/60	46
57.123 Antimicrobial Use and Resistance (AUR)—Microbiology Data Electronic Upload Specification Tables	5,500	12	5/60	5,500
57.124 Antimicrobial Use and Resistance (AUR)—Pharmacy Data Electronic Upload Specification Tables	5,500	12	5/60	5,500
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	26/60	46,150
57.126 MDRO or CDI Infection Form	720	12	30/60	4,320
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60	39,875
57.128 Laboratory-identified MDRO or CDI Event	4,800	12	20/60	19,200
57.129 Adult Sepsis	50	12	25/60	250
57.132 Patient Safety Component Digital Measure Reporting Plan (HOB, HT–CDI, VTE, Adult Sepsis, RPS, NVAP)—IT Initial Set up	5,500	1	1,620/60	148,500
57.132 Patient Safety Component Digital Measure Reporting Plan (HOB, HT–CDI, VTE, Adult Sepsis, RPS, NVAP)—IT Yearly Maintenance	5,500	1	1,200/60	110,000
57.132 Patient Safety Component Digital Measure Reporting Plan (HOB, HT–CDI, VTE, Adult Sepsis, RPS, NVAP)—Infection Preventionist	5,500	4	10/60	3,667
57.132 Patient Safety Digital Reporting Plan (RPS CSV)	5,500	365	2/60	66,917
57.137 Long-Term Care Facility Component—Annual Facility Survey	6,270	1	128/60	13,376
57.138 Laboratory-identified MDRO or CDI Event for LTCF	286	24	20/60	2,288
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	738	12	10/60	1,476
57.140 Urinary Tract Infection (UTI) for LTCF	373	24	35/60	5,222
57.141 Monthly Reporting Plan for LTCF	546	12	5/60	546
57.142 Denominators for LTCF Locations	724	12	35/60	5,068
57.143 Prevention Process Measures Monthly Monitoring for LTCF	434	12	5/60	434
57.144 Resident Respiratory Pathogens Even Form	16,500	24	25/60	165,000
57.145 Long Term Care Antimicrobial Use (LTC–AU) Module CDA	16,500	12	5/60	16,500
57.150 LTAC Annual Survey	395	1	102/60	672
57.151 Rehab Annual Survey	395	1	102/60	672
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333
57.211 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	8,000	8	60/60	64,000
57.214 Annual Healthcare Personnel Influenza Vaccination Summary	22,000	1	120/60	44,000
57.215 Seasonal Survey on Influenza Vaccination Programs for Healthcare Personnel	15,426	1	45/60	11,570
57.300 Hemovigilance Module Annual Survey	63	1	85/60	89
57.301 Hemovigilance Module Monthly Reporting Plan	108	12	1/60	22
57.302 Hemovigilance Module Monthly Incident Summary	9	12	30/60	54
57.303 Hemovigilance Module Monthly Reporting Denominators	102	12	70/60	1,428
57.305 Hemovigilance Incident	13	77	10/60	167
57.306 Hemovigilance Module Annual Survey—Non-acute care facility	20	1	35/60	12
57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction	8	2	20/60	5
57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction	50	11	20/60	183

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number & name	Number of respondents	Number of responses per respondent	Avg. burden per response (min./hour 60)	Total burden (hours)
57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction	9	2	20/60	6
57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction	19	5	20/60	32
57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction	85	13	20/60	368
57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction	23	3	20/60	23
57.313 Hemovigilance Adverse Reaction—Infection	2	2	20/60	1
57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura	1	1	20/60	0.33
57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea	18	3	20/60	18
57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease	1	1	20/60	0.33
57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury	1	1	20/60	0.33
57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload	40	4	21/60	56
57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction	15	3	20/60	15
57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction	39	3	20/60	39
57.400 Outpatient Procedure Component — Annual Ambulatory Surgery Center Survey	350	1	10/60	58
57.401 Outpatient Procedure Component—Monthly Reporting Plan	350	12	10/60	700
57.402 Outpatient Procedure Component Same Day Outcome Measures	50	1	40/60	33
57.403 Outpatient Procedure Component—Denominators for Same Day Outcome Measures	50	400	20/60	6,667
57.404 Outpatient Procedure Component—SSI Denominator	300	100	20/60	10,000
57.405 Outpatient Procedure Component—Surgical Site (SSI) Event	300	36	40/60	7,200
57.408 Monthly Survey Patient Days & Nurse Staffing	2,500	12	300/60	150,000
57.500 Outpatient Dialysis Center Practices Survey	6,900	1	150/60	17,250
57.501 Dialysis Monthly Reporting Plan	7,400	12	5/60	7,400
57.502 Dialysis Event	7,400	30	50/60	185,000
57.503 Denominator for Outpatient Dialysis	7,400	12	10/60	14,800
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1,730	12	60/60	20,760
57.507 Home Dialysis Center Practices Survey	550	1	65/60	596
57.600 Neonatal Component FHIR Measure—Late Onset Sepsis Meningitis (LOSMEN) Module—IT Initial Set up	5,500	1	1620/60	148,500
57.600 Neonatal Component FHIR Measure—Late Onset Sepsis Meningitis (LOSMEN) Module—IT Yearly Maintenance	5,500	1	1,200/60	110,000
57.600 Neonatal Component FHIR Measure—Late Onset Sepsis Meningitis (LOSMEN) Module—Infection Preventionist	5,500	6	6/60	3,300
57.600 Neonatal Component Late Onset Sepsis Meningitis (LOSMEN) Module CDA Data Collection—Infection Preventionist	5,500	12	2/60	2,200
57.601 Late Onset Sepsis/Meningitis Denominator Form: Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60	150
57.602 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	6/60	180
57.700 Medication Safety—Digital Measure Reporting Plan (HYPO, HAKI, ORAE)—IT Initial Set up	5,500	1	1,620/60	148,500
57.700 Medication Safety—Digital Measure Reporting Plan (HYPO, HAKI, ORAE)—IT Yearly Maintenance	5,500	1	1,200/60	110,000
57.700 Medication Safety—Digital Measure Reporting Plan (HYPO, HAKI, ORAE)—Infection Preventionist	5,500	4	10/60	3,667
57.701 Glycemic Control Module—HYPO Annual Survey	10	1	120/60	20
Billing Code Data: 837I Upload	5,500	4	5/60	1,833
Total	.....	.....	.....	3,635,534

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08597 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–24CR]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Global Public Health Data Innovation Performance Monitoring'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 9, 2024 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Global Public Health Data Innovation Performance Monitoring (OMB Control Number pending)—New—Global Health Center (GHC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Global Public Health Data Innovation (GPHDI) initiative, led by the U.S. Centers for Disease Control and Prevention (CDC), aims to equip government decision makers with timely, accurate, and comprehensive public health data to effectively prevent, detect, and respond to public health threats. Challenges, such as limited data access, non-standardization, workforce limitations, and gaps in data systems and governance, often hinder the optimal use of data in public health response efforts. To overcome these challenges, GPHDI focuses on strengthening global outbreak response, pandemic preparedness, and surveillance through improved data availability and utilization. This is achieved by modernizing data systems and processes at all levels.

GPHDI is made possible by the American Rescue Plan Act passed by the U.S. Congress in 2021 and is rooted in key strategic pillars within CDC, namely the Data Modernization Initiative (DMI) and the Global Digital Health Strategy (GDHS). DMI is an agency-wide initiative aimed at improving data systems infrastructure within the United States, offering valuable insights and artifacts that can be adapted and leveraged for the global context of the GPHDI initiative. The goal of DMI is to get better, faster, actionable insights for decision making at all levels of public health. Complementing this, the GDHS incorporates inputs from a multi-partner engagement process, enhancing the strategic approach of the initiative.

GPHDI is currently a three-year investment that builds on an existing foundation laid by various country governments, donor agencies, and multilateral organizations. This investment is specifically allocated to advance the initiative in 10 selected countries, including Kenya, Sierra Leone, Uganda, and Zambia in Africa; Colombia and Paraguay in the South American Region; Georgia and Ukraine in Eastern Europe; Thailand in the Central Asia Region; and Honduras in the Central American Region.

This data collection is aimed at monitoring and assessing the contributions of current GPHDI investments in data modernization and digital public health infrastructure towards improving data availability to prevent, detect, and respond to public health threats in the selected countries. The indicators to be collected as shown in the data collection instrument include both structured response-type questions (Yes-No answers, coded answers) and narrative response-type questions. CDC contractors, RTI International (RTI) will conduct the interviews and CDC-funded implementing partners (IPs) monitoring and evaluation (M&E) point of contacts will provide responses to the indicators based on their funded activities. RTI will document the responses from the interviews using an instance of CDC RedCap. Interviews will be conducted in a live one-on-one session between RTI and identified M&E point of contacts at the funded IPs. No patient-level or individual level or identifiable data will be collected for this project.

CDC requests OMB approval for an estimated 64 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Implementing partners (Monitoring and evaluation point of contacts).	Monitoring question guide	32	1	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08591 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–24ER; Docket No. CDC–2024–0029]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Direct Reading Methodologies, Sensors, and Robotics Technology Assessment in Lab/Simulator-based Settings. The proposed data collection will allow NIOSH to assess the safety and health considerations of these rapidly changing direct reading methods, sensor, and robotics technologies.

DATES: CDC must receive written comments on or before June 24, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0029 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Direct Reading, Sensor, and Robotics Technology Assessment in Lab/Simulator-based Settings—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), is requesting approval of a new Generic information collection for a period of three years under the project titled, Direct Reading Methodologies, Sensor Technologies, and Robotics Technology Assessment in Lab/Simulator-based Settings. NIOSH is a Federal institute that operates within the CDC specifically dedicated to generating new knowledge in the field of occupational safety and health and responsible for transferring that knowledge into practice for the betterment of workers. Given NIOSH's mission to develop new knowledge, the Institute is uniquely positioned to evaluate potential benefits and risks relative to occupational safety and health issues of the 21st century workplace, work, and workforce—also discussed as the Future of Work (FOW). Areas requiring detailed attention and advancement include research and development in artificial intelligence, robotics, and sensor technologies. NIOSH has established alliances and partnerships with other Federal agencies and external partners to collaborate and share technical knowledge to improve awareness around workplace hazards and appropriate safeguards as it relates to technology. Consequently, NIOSH created two Centers charged with leading and coordinating these FOW efforts, with a focus on technology assessment and integration in the workplace that revolves around emerging recommendations and standards in advancing automation.

First, in 2014, the NIOSH Center for Direct Reading and Sensor Technologies (CDRST) was established to research and develop recommendations on the use of 21st century technologies in occupational safety and health. Both direct-reading methodologies and sensors are used to detect and monitor hazardous conditions, to assess and document intervention strategies, and especially to immediately trigger alarms in the event of unsafe conditions. Examples of direct reading and sensor technologies include real-time personal monitoring, wearable monitors, and exoskeletons including wearable robots.

Second, in 2017, NIOSH established the Center for Occupational Robotics Research (CORR) to study the nature of robots in the workplace, conduct workplace interventions to prevent robot-related worker injuries, and develop guidance for safe interactions between humans and robots. There are several common types of robots used in occupational environments—traditional industrial robots; professional or service robots; collaborative robots; and mobile

robots (*e.g.,* drones and powered exoskeletons). In most cases, NIOSH laboratories including virtual reality (VR) facilities, are used to conduct this research in a safe and controlled environment. Within these studies, human factors, safety engineering, and test strategies are utilized to provide feedback about the utility of various robotics technology in the workplace to inform design, as well as possible standards.

Direct reading methodologies, sensor technologies, and robotics technology play important roles in advancing automation to keep many workers within various industries safe while performing their professional duties but rapidly evolve and change in scope and use. NIOSH requests a Generic information collection package for assessing the safety and health considerations of these rapidly changing direct reading methods, sensor, and robotics technologies.

Different types of data will be collected around these technologies including: (1) body function assessments to identify the validity and reliability of direct reading, sensor, and robotic technologies; (2) physiological assessments to identify the impact of direct reading, sensor, and robotic technologies on worker outputs; (3) perceived knowledge, attitudes, skills, and other personal attributes to assess risks associated with the use and integration of direct reading, sensor, and robotics technologies among workers; and (4) barriers that workers face while using or interacting with direct reading methodologies, sensor technologies, and robotic technologies to prevent unintended safety and health consequences—including adoption and maintenance challenges. Collectively, this information will be used to inform research, development, and integration recommendations to advance the nation's FOW needs. These data collection efforts will most often occur in controlled laboratory space, including virtual reality space that simulates these technologies. In some cases (*e.g.,* survey or follow-up interview administration) data collection may occur electronically.

Respondents are expected to be reflective of the full spectrum of the U.S. workforce and from industries that rely heavily on direct reading methodologies, sensor technologies, and robotics technologies to protect workers (*e.g.,* public safety and emergency response, manufacturing, retail and trade, construction, mining, and oil and gas). Expected respondents include any worker who has experience with, is required to use, or willing to use and provide feedback on any sort of direct reading method, sensor, or robotics technology in the workplace—these could be wearable or non-wearable. Common job roles that wear or interact with such technology include construction workers, manufacturing workers, oil gas and extraction workers, mineworkers, retail workers, maintenance workers, manufacturing workers, fire chiefs/firefighters, law enforcement officers, and any industrial hygiene or occupational safety and health professional who oversees the integration and use of new technologies in the workplace. Recruitment for laboratory studies includes individuals from the general working population that represent high-hazard industries (*e.g.,* construction, manufacturing). These individuals are also all adults between the ages of 18 and 65 years.

CDC requests OMB approval for an estimated 205,002 total burden hours with an estimated annual burden of 68,334 hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Members of the general public who represent a variety of industrial sectors [1].	Informed Consent	4,000	1	5/60	334
	Pre-Screening Health Questionnaire: Standardized form with decision logic allowing some questions to be omitted.	4,000	2	15/60	2,000
	Demographics Questionnaire: Standardized form with decision logic allowing some questions to be omitted.	4,000	1	15/60	1,000
	Job Survey: Occupational tasks, postures used, duration of exposure, etc.	4,000	1	15/60	1,000
	Pre- and Post-Assessments: Determine changes in knowledge, skills, and abilities as it related to efficacy, confidence, and perceived competence in technology assessment/intervention (this could be strictly quantitative or semi-structured).	4,000	2	15/60	2,000
	Anthropometric Measurements: Calipers/digital measuring of facial and body dimensions with and without gear (*e.g.,* chest depth; foot breadth with and without proper personal protective equipment) to assess functional integration of wearables and other sensors.	4,000	12	5/60	4,000

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Physiological Measurements: Measurements recorded using chest worn heart rate monitor strap, blood pressure cuff/strap, COSMED Kb5 or similar, SQ2020–1F8 temperature logger, TOSCA 500 pulse oximeter, Koken breathing waveform recording mask, MOXY muscle oxygenation strap sensor, neurophysiological measures including Electroencephalography (EEG), and Functional near-infrared spectroscopy (fNIRS), etc.	4,000	4	60/60	16,000
	Perceived Rate of Exertion: using validated perceived exertion scales (*e.g.,* Borg Ratings).	3,000	12	5/60	3,000
	Body Function Assessments: Measurements taken (e.g., on the low back, neck, shoulder, arm, etc.) to conduct strength testing, range of motion testing, reference or maximum voluntary exertions, endurance testing with different direct reading, wearable sensor, and robotics technologies.	3,000	6	30/60	9,000
	Motion Measurement Cameras: Camera with motion amplification technology (*e.g.,* Iris M, Moasure One, etc.) that can measure deflection, displacement, movement, and vibration not visible to the human eye using biomechanical markers for motion capture.	2,000	12	15/60	6,000
	Perceived Usability Assessments: Close- and open-ended questions to determine system usability including usability scales, mental workload, body part discomfort, and contact stress experiences of new direct reading, sensor, and robotics technologies (lab- and virtual reality-based).	4,000	6	10/60	4,000
	Self-Perception Surveys and other Structured Questions: Perceived comfort level with technology, perceived safety and trust level with technology, perceived fatigue while interacting with technology, etc.	4,000	6	10/60	4,000
	Biomechanics measurements: Force plate, strain gauges, stopwatch, accelerometers (including dataloggers), electromyography sensors human/equipment interaction forces, whole-body motion, Electromyography (EMG) for muscle activity, Near-infrared spectroscopy (NIRS) for muscle oxygenation, etc.	2,000	4	30/60	4,000
	Task Performance Measures: Measures recorded using various virtual reality systems (*e.g.,* Vive, Meta quest) and components (*e.g.,* controllers) that quantify the subjects' performance such as time to complete, errors, movement path, and omissions.	2,000	12	15/60	6,000
	Eye Tracking Measures: Recorded using various virtual reality glasses (*e.g.,* Ergoneers) to assess eyes-off-task time and recognition in response to simulated environments designed to assess integration of new robotic technologies and design set-up.	2,000	12	15/60	6,000
	.....	.....	.....	.....	68,334

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08596 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–24EZ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request (ICR) titled ''Workplan Templates for Ten Regional Centers to Enhance Public Health Preparedness and Response'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 19, 2023 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow 30 days for public and affected agency comments on new and updated information collection instruments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Workplan Templates for Ten Regional Centers to Enhance Public Health Preparedness and Response—New—Office of Readiness and Response (ORR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since 2001, CDC supported development implementation, evaluation, translation and dissemination of research findings, strategies, and interventions to improve public health preparedness and response systems, infrastructures, processes, and practices. This includes the long-standing PHEP cooperative agreement, CDC's Public Health Crisis Response Funding, and support for applied research and evaluation, metrics, measures, tools, and training development. In 2021, with contract support, CDC's Office of Applied Research (OAR) initiated 12 scoping reviews, six landscape analyses, and one systematic review to conduct deeper dives into topics such as trust in public health preparedness and response, emergency communications strategies with people with limited English proficiency, public health emergency preparedness and response (PHEPR) practice in rural and tribal communities, and use of health equity coordinators in incident management. The results of these reviews show great breadth in the PHEPR field as it relates to knowledge available to support current practice and highlights the need to expand knowledge to address specific gaps. These needs and gaps may differ across geographical regions and within those regions at the state or local level. To address needs to increase the uptake of evidence-based interventions, in December 2022, through section 2231 of the federal appropriations for fiscal year 2023, CDC was directed to support not fewer than 10 Centers for Public Health Emergency Preparedness and Response that are equally distributed among the geographical regions of the U.S. (referred to as the ''network of centers'').

This project aims to establish up to 10 centers across the designated Health and Human Services (HHS) regions for public health preparedness and response (PHPR). The goal is to improve PHPR practices by increasing the uptake of evidence-based strategies and interventions (EBSIs) that align with the needs of the communities involved. This will be achieved through: (1) the development of a five-year workplan that covers known strategies or interventions, plans to implement each strategy or intervention, or the development and evaluation of new approaches in PHPR; (2) the use of a Cooperative Agreement Work Plan Template to monitor performance of activities throughout the funding period; and (3) the use of an Evaluation Work Plan Template to support evaluation of implemented work plan activities.

The Five-Year Regional Work Plan addresses: (1) focus areas and objectives across State, Tribal, Local, and Territorial (STLT) and relevant partners that would benefit from use of new or enhanced PHPR EBSIs; (2) activities to meet objectives; (3) prioritized EBSIs to implement; (4) capability and capacity of STLT health departments and relevant partners to implement and evaluate activities; and (5) regional sustainability for implementation of evidence-based practice beyond the five-year period. Contractors will collect information from the 10 HHS regional Strategic Coordinators to develop focus areas, objectives, or activities for individualized workplans to advance the implementation of EBSIs for PHPR activities.

This proposed project also includes two additional instruments including: (1) an Evaluation Work Plan Template that provides background information needed to understand approaches in evaluating selected strategies or intervention activities; and (2) a Cooperative Agreement Work Plan Template that serves as a performance monitoring instrument that supports tracking of project activities throughout the performance period.

OMB approval is sought for three years. The estimated annualized burden for this information collection is 150 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
HHS Regional Strategic Coordinators	Office of Readiness and Response—Regional Centers for Public Health Preparedness and Response: Five-Year Regional Workplan Template FY2024–2030.	10	1	5
HHS Regional Strategic Coordinators	Office of Readiness and Response—Evaluation Work Plan Template.	10	1	8
HHS Regional Strategic Coordinators	Office of Readiness and Response—Cooperative Agreement Work Plan.	10	1	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08592 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0909]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Diabetes Prevention Recognition Program (DPRP)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on 12/15/2023 to obtain comments from the public and affected agencies. CDC received 19 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the attention of: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of the notice of publication.

Proposed Project

CDC Diabetes Prevention Recognition Program (DPRP) (OMB Control No. 0920–0909, Exp. 04/30/2024)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Division of Diabetes Translation (DDT) established and administers the National DPP's Diabetes Prevention Recognition Program (DPRP), which recognizes organizations that deliver a diabetes prevention program according to evidence-based requirements set forth in the Centers for Disease Control and Prevention's Diabetes Prevention Recognition Program Standards and Operating Procedures (DPRP Standards). Additionally, the Centers for Medicare & Medicaid Services (CMS) Medicare Diabetes Prevention Program (MDPP) expansion of CDC's National DPP was announced in early 2016, when the Secretary of Health and Human Services (HHS) determined that the Diabetes Prevention Program met the statutory criteria for inclusion in Medicare's expanded list of health care services for beneficiaries (*https://cmmi.my.site.com/mdpp/*). This was the first time a preventive service model from the CMS Innovation Center was expanded into Medicare. After extensive testing of this model in 17 sites across the U.S. in 2014–2016, CMS proposed the MDPP in sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh sec. 424.59), authorizing CDC-recognized organizations to prepare for enrollment as MDPP suppliers beginning in January 2018 in order to bill CMS for these services. Only organizations in good standing with the CDC DPRP are eligible as MDPP suppliers. CDC continues to work with CMS to support the MDPP.

CDC requests an additional three years of OMB approval to continue collecting the information needed to administer the DPRP and provide information needed by CMS to support the MDPP benefit. Based on experience with the DPRP from 2011–2023, including data analysis and feedback from applicant organizations and internal and external partners, CDC plans to revise the DPRP Standards and the associated information collection.

Key changes are a direct result of DPRP data analyses, recent literature reviews, and discussion with national DPP stakeholders, including those serving socially vulnerable populations. Key changes to the evaluation data collection instrument allow for the collection of participant zip codes (for

aggregate reporting only; not to be reported for each individual participant); an OMB-recommended six-point disability variable (not tied to CDC recognition and with a variable option of 'Participant chose not to respond'); a health equity-related social determinants of health (SDOH) variable set (to assess whether there was a social needs assessment conducted; key SDOH issues identified; and whether any action was taken; not tied to CDC recognition); a Middle Eastern or North African write-in option within the current race/ethnicity variable; and two new options for the current payersource variable.

Key changes to the application data collection instrument allow for a yes/no drop-down question asking if an organization's zip code is in an area of high social vulnerability based on the Social Vulnerability Index, which would permit an in-person organization to be fast-tracked to Preliminary recognition status to allow the organization to apply to CMS to become an MDPP supplier; revisions to the combination delivery mode to include an option for in-person delivery with a distance learning component; and collection of a projected program start-date.

During the period of this Revision, CDC estimates receipt of approximately 200 DPRP application forms per year from new organizations. The estimated burden per one-time application response is one hour (annualized to 200 hours). In addition, CDC estimates receipt of semi-annual evaluation data submissions from the same 200 additional organizations per year, estimated at two hours per response. The total estimated average annualized evaluation burden for new respondents is 2,400 hours. This includes an estimate of the time needed to extract and compile the required data records and fields from an existing electronic database, review the data, and enter the data via the DPRP Data Portal. CDC also has 1,500 currently recognized organizations that will continue to submit semi-annual evaluation data. These organizations are reflected in Supporting Statement B within this OMB revision.

The estimated burden per response is moderate, since the information requested for CDC recognition is routinely collected by most organizations that deliver the National DPP lifestyle change program for their own internal evaluation and possible insurance reimbursement purposes, including the MDPP benefit. Participation in the DPRP is voluntary, data are de-identified, no personally identifiable information (PII) is collected by CDC, and there are no costs to respondents other than their time. CDC is requesting a three-year approval. The total estimated annualized burden is 7,800 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Public sector organizations that deliver the National DPP lifestyle change program.	DPRP Application Form	80	1	1
	DPRP Evaluation Data	740	2	2
Private sector organizations that deliver the National DPP lifestyle change program.	DPRP Application Form	120	1	1
	DPRP Evaluation Data	1,160	2	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–08593 Filed 4–22–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10434]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services.

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited clearance process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that may be submitted under that umbrella. This notice is intended to advise the public of our intent to extend OMB's approval of our MACPro (Medicaid and CHIP Program) umbrella and all of the individual generic collection of information requests that fall under that umbrella. This notice also provides the public with general instructions for obtaining documents that are associated with such collections and for submitting comments.

DATES: Comments must be received by May 23, 2024.

ADDRESSES:

Submitting Comments: When commenting, please reference the applicable collection's CMS ID number and/or the OMB control number (both numbers are listed below under the **SUPPLEMENTARY INFORMATION** caption). To be assured consideration, comments and recommendations must be submitted in any one of the following ways and by the applicable due date:

1. *Electronically.* We encourage you to submit comments through the Federal eRulemaking portal at the applicable web address listed below under the **SUPPLEMENTARY INFORMATION** caption under ''Docket Information.'' If needed, instructions for submitting such comments can be found on that website.

2. *By regular mail.* Alternatively, you can submit written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs (OSORA), Division of Regulations Development, Attention: CMS–10434/OMB 0938–1188, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Obtaining Documents: To obtain copies of supporting statements and any related forms and supporting documents for the collections listed in this notice, please refer to the following instructions:

1. We encourage you to access the Federal eRulemaking portal at the applicable web address listed below under the **SUPPLEMENTARY INFORMATION** caption under ''Docket Information.'' If needed, follow the online instructions

for accessing the applicable docket and the documents contained therein.

FOR FURTHER INFORMATION CONTACT: For general information contact William N. Parham at 410–786–4669. For policy related questions, contact the individual listed below under the **SUPPLEMENTARY INFORMATION** caption under ''Docket Information.''

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). Generally, it applies to voluntary and mandatory requirements that are related to any one or more of the following activities: the collection of information, the reporting of information, the disclose of information to a third-party, and/or recordkeeping.

While there are some exceptions (such as collections having non-substantive changes and collections requesting emergency approval) section 3506(c)(2)(A) of the PRA requires Federal agencies to publish 60- and 30-day notices in the **Federal Register** and solicit comment on each of its proposed collections of information, including: new collections, extensions of existing collections, revisions of existing collections, and reinstatements of previously approved collections before submitting such collections to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Interested parties are invited to submit comments regarding our burden estimates or any other aspect of the collection, including: the necessity and utility of the proposed information collection for the proper performance of our agency's functions; the accuracy of burden estimates; 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. See **DATES** and **ADDRESSES** for instructions for submitting comments.

While we will review all comments received, we may choose not to post off-topic or inappropriate comments. Otherwise, all comments will be posted without edit under the applicable docket number, including any personal information that the commenter provides. Our response to such comments will be posted at reginfo.gov under the applicable OMB control number.

Medicaid and CHIP Program (MACPro)

At this time, MACPro is made up of the main umbrella (see collection number 1 in the following list) and nine individual generic collections of information (see collection numbers 2 through 10 in the following list). Details such as the collection's requirements and burden estimates can be found in the collection's supporting statement and associated materials (see **ADDRESSES** for instructions for obtaining such documents).

Docket Information

1. Title: Medicaid and CHIP Program (MACPro)

Type of Request: Revision of a currently approved collection.
CMS ID Number: CMS–10434.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0080.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0080.
For Policy Related Questions, Contact: William N. Parham at 410–786–4669.

2. Title: Initial Application

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #1.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0081.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0081.
For Policy Related Questions, Contact: Stephanie Bell at 410–786–0617.

3. Title: CHIP State Plan Eligibility

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #2.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0082.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0082.
For Policy Related Questions, Contact: Stephanie Bell at 410–786–0617.

4. Title: Alternative Benefit Plans (ABPs)

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #3.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0083.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0083.
For Policy Related Questions, Contact: Adrienne Delozier at 410–786–0278.

5. Title: Medicaid State Plan Eligibility

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #15.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0090.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0090.
For Policy Related Questions, Contact: Suzette Seng at 410–786–4703.

6. Title: Health Home State Plan Amendment (SPA)

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #22.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0084.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0084.
For Policy Related Questions, Contact: Mary Pat Farkas at 410–786–5731.

7. Title: Medicaid Adult and Child Core Set Measures

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #26.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0085.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0085.
For Policy Related Questions, Contact: Virginia (Gigi) Raney at 410–786–6117.

8. Title: Maternal and Infant Health Quality

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #45.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0086.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0086.
For Policy Related Questions, Contact: Virginia (Gigi) Raney at 410–786–6117.

9. Title: Health Home Core Sets

Type of Request: Extension of a currently approved collection.
CMS ID Number: CMS–10434 #47.
OMB Control Number: 0938–1188.
eRulemaking Docket ID Number: CMS–2023–0087.
Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0087.
For Policy Related Questions, Contact: Mary Pat Farkas at 410–786–5731.

10. Title: Medicaid Extended Postpartum Coverage and Continuous Eligibility for Children

Type of Request: Extension of a currently approved collection.

CMS ID Number: CMS–10434 #77.

OMB Control Number: 0938–1188.

eRulemaking Docket ID Number: CMS–2023–0088.

Docket Web Address: https://www.regulations.gov/docket/CMS-2023-0088.

For Policy Related Questions, Contact: Alexa Turner at 410–786–8823.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–08658 Filed 4–22–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Community Services Block Grant (CSBG) Model Tribal Plan and Application (New Collection)

AGENCY: Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Community Services (OCS), Administration for Children and Families (ACF), requests an approval of the Community Services Block Grant (CSBG) Model Tribal Plan.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 677 of the CSBG Act requires Indian tribes or tribal organizations to submit an application and plan (CSBG Model Tribal Plan). The CSBG Model Tribal Plan must meet statutory requirements prior to OCS awarding CSBG tribal grant recipients with CSBG funds. Tribal grant recipients have the option to submit a detailed plan annually or biannually. Tribal grant recipients that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur. The CSBG Model Tribal Plan has been used in previous years without OMB approval. To come into compliance with the PRA, ACF is submitting the CSBG Model Tribal Plan as a new request to OMB.

Respondents: Tribal grant recipients (*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
CSBG Model Tribal Plan	66	1	10	660

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 677, Pub. L. 105–285, 112 Stat. 2742 (42 U.S.C. 9911)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–08668 Filed 4–22–24; 8:45 am]

BILLING CODE 4184–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1786]

PAI Holdings, LLC DBA Pharmaceutical Associates, Inc., et al.; Withdrawal of Approval of 23 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 23, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 007959	Tensilon (edrophonium chloride) Injection, 10 milligrams (mg)/milliliter (mL). Tensilon Preservative Free (edrophonium chloride) Injection, 10 mg/mL.	PAI Holdings, LLC dba Pharmaceutical Associates, Inc., 1700 Perimeter Rd., Greenville, SC 29605.
NDA 009900	Cortef (hydrocortisone cypionate) Oral Suspension, Equivalent to (EQ) 10 mg base/5 mL.	Pharmacia and Upjohn Co., 66 Hudson Blvd. East, New York, NY 10001.
NDA 015923	Haldol (haloperidol lactate) Injection, EQ 5 mg base/mL	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, Raritan, NJ 08869.
NDA 017090	Tofranil-PM (imipramine pamoate) Capsules, EQ 75 mg hydrochloride (HCl), EQ 100 mg HCl, EQ 125 mg HCl, and EQ 150 mg HCl.	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119.
NDA 018309	Topicort LP (desoximetasone) Emollient Cream, 0.05%	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
NDA 018401	Buprenex (buprenorphine HCl) Injection, EQ 0.3 mg base/mL	Indivior Inc., 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235.
NDA 019201	Voltaren (diclofenac sodium) Delayed-Release Tablets, 25 mg, 50 mg, and 75 mg.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 019425	Trandate (labetalol HCl) Injection, 5 mg/mL	Sebela Ireland Limited, c/o Sebela Pharmaceuticals Inc., 645 Hembree Pkwy., Suite 1, Roswell, GA 30076.
NDA 020142	Cataflam (diclofenac potassium) Tablets, 25 mg and 50 mg ..	Novartis Pharmaceuticals Corp.
NDA 020254	Voltaren XR (diclofenac sodium) Extended-Release Tablets, 100 mg.	Do.
NDA 020631	Morphine Sulfate Injection, 1 mg/mL and 2 mg/mL	SpecGx LLC.
NDA 020768	Zomig (zolmitriptan) Tablets, 2.5 mg and 5 mg	iPR Pharmaceuticals, Inc., c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 020897	Ditropan XL (oxybutynin chloride) Extended-Release Tablets, 5 mg, 10 mg, and 15 mg.	Janssen Pharmaceuticals, Inc.
NDA 020945	Norvir (ritonavir) Capsules, 100 mg	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.
NDA 021226	Kaletra (lopinavir/ritonavir) Capsules, 133.3 mg/33.3 mg	Do.
NDA 021231	Zomig-ZMT (zolmitriptan) Orally Disintegrating Tablets, 2.5 mg and 5 mg.	iPR Pharmaceuticals, Inc., c/o AstraZeneca Pharmaceuticals LP.
NDA 021360	Sustiva (efavirenz) Tablets, 300 mg and 600 mg	Bristol-Myers Squibb Company, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 022484	Onmel (itraconazole) Tablets, 200 mg	Sebela Ireland Limited, c/o Sebela Pharmaceuticals Inc.
NDA 050679	Maxipime (cefepime HCl) for Injection, EQ 500 mg base/vial, EQ 1 gram base/vial, and EQ 2 gram base/vial.	Hospira Inc, 275 North Field Dr., Bldg. H1–3S, Lake Forest, IL 60045.
NDA 203696	Lupaneta Pack (leuprolide acetate injection and norethindrone acetate Tablets), 3.75 mg/vial;5 mg and 11.25 mg/vial;5 mg.	AbbVie Endocrinology Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 206302	Byvalson (nebivolol HCl/valsartan) Tablets, EQ 5 mg base/80 mg.	AbbVie Inc.
NDA 208042	Cassipa (buprenorphine HCl/naloxone HCl) Sublingual Film, EQ 16 mg base/EQ 4 mg base.	Teva Pharmaceuticals USA, Inc., 577 Chipeta Way, Salt Lake City, UT 84108.
NDA 208437	Lonhala Magnair Kit (glycopyrrolate) Inhalation Solution, 25 microgram/mL.	Sumitomo Pharma America, Inc., 84 Waterford Dr., Marlborough, MA 01752.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 23, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on May 23, 2024, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08657 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0946]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on the FDA's website entitled ''Postmarketing Requirements and Commitments: Reports'' (*https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants are required to, or have committed to, conduct and for which annual status reports have been submitted. Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drug products and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application, as applicable. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2022 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year 2022 (*i.e.,* as of September 30, 2022). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) the number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year (FY) of establishment [2] (FY2016 to FY2022) for PMRs and PMCs open at the end of FY2022, or those closed within FY2022. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.html.*

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08649 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1055]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic clearance to collect information to support social and behavioral research used by FDA about drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by June 24, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 24, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2024–N–1055 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methodology to achieve these goals: (1) creation and validation of survey instruments; (2) use of techniques to evaluate sampling and recruitment methods; (3) evaluation of the validity and reliability of survey instruments; (4) individual in-depth interviews, (5) general public focus group interviews, (6) intercept interviews, (7) self-administered surveys, (8) gatekeeper surveys, and (9) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

• Obtaining useful, valid, and reliable information for the development of variables and measures for formulating the basic objectives of social and behavioral research and

• Successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Further, in addition to overseeing the safety of drug products when used according to approved drug labeling or as directed by a healthcare provider, the Center for Drug Evaluation and Research (CDER) conducts studies on topics related to the safe and effective use of drug products, and emerging safety issues in areas such as nonmedical use of approved drug products, use of unapproved and falsified (*i.e.,* counterfeit, fake) drug products, use of botanical substances (*e.g.,* cannabis derived products), controlled substance prescribing decisions, bystander response to drug overdoses, and potentially false or misleading information about drug products. Reliable data on these and related topics are a critical first step to understanding whether further studies or action is needed to protect public health.

Because often data on these topics are not collected as part of routine healthcare delivery or via established Federal surveys, FDA requires the development and validation of novel instruments (*i.e.,* interview and focus group guides, questionnaires) and approaches to gathering data on emerging safety issues the methods used to create and validate these instruments may include interviews, focus groups, small group discussions, pilot and test/re-test survey launches, and external validation against benchmark surveys. In conducting research in these areas, FDA will need to employ the following validation methodology: (1) research to assess knowledge, perceptions, and experiences related to topics in the above-mentioned areas with specific target populations; (2) techniques to evaluate sampling and recruitment methods; and (3) evaluations of the validity and reliability of survey questionnaires in target populations.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	126,770	1	126,770	0.25 (15 minutes)	31,693

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, our burden estimate for this information collection reflects an overall increase of 17,300 responses with a corresponding increase of 4,325 hours. We attribute this adjustment to the need to validate information in specific areas.

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08655 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting—Guardant Shield Blood Collection Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) announces a forthcoming public advisory committee meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on May 23, 2024, from 9:30 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Jarrod.Collier@fda.hhs.gov,* 240–672–5763, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.*htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On May 23, 2024, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Shield test by Guardant Health, Inc. The proposed indication for use statement is as follows: The Shield test is a qualitative in vitro diagnostic test intended to detect colorectal cancer derived alterations in cell-free DNA from blood collected in the Guardant Blood Collection Kit. Shield is intended for colorectal cancer screening in individuals at average risk of the disease, age 45 years or older. Patients with an ''Abnormal Signal Detected'' may have colorectal cancer or advanced adenomas and should be referred for colonoscopy evaluation. Shield is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals. The test is performed at Guardant Health, Inc.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will

be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 10, 2024. Oral presentations from the public will be scheduled on May 23, 2024, between approximately 1:45 p.m. and 2:45 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 7, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 8, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: April 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08656 Filed 4–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 24, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program Client-Level Data Reporting System, OMB No. 0906–0039—Revision.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), authorized under Title XXVI of the Public Health Service Act, is administered by the HIV/AIDS Bureau within HRSA. HRSA awards funding to recipients in areas of the greatest need to respond effectively to the HIV epidemic, with an emphasis on providing life-saving and life-extending medical care, treatment, and support services for people with HIV in the United States.

The RWHAP reporting requirements include the annual submission of client-level data in the Ryan White HIV/AIDS Program Services Report (RSR). The RSR is designed to collect information from grant recipients and their subawarded service providers, funded under Parts A, B, C, and D of the RWHAP statute.

HRSA is requesting a revision of the current RSR with one proposed update:

Current Questions

- Within your organization/agency, identify the number of physicians, nurse practitioners, or physician assistants who obtained a Drug Addiction Treatment Act of 2000 waiver to treat opioid use disorder with medication assisted treatment (MAT), [*e.g.,* buprenorphine, naltrexone] specifically approved by the U.S. Food and Drug Administration.
- How many of the above physicians, nurse practitioners, or physician assistants prescribed MAT (*e.g.,* buprenorphine, naltrexone) for opioid use disorders in the reporting period?

Proposed Change to Question in 2024 RSR Form

- How many physicians, nurse practitioners, or physician assistants in your organization prescribed medications for opioid use disorder (MOUD) [*e.g.,* buprenorphine, naltrexone] for opioid use disorders during the reporting period?

Need and Proposed Use of the Information: The RWHAP statute specifies HRSA's responsibilities in administering grant funds, allocating funding, assessing HIV care outcomes (*e.g.,* viral suppression), and serving particular populations. The RSR collects data on the characteristics of RWHAP-funded recipients, their contracted service providers, and the patients or clients served. The RSR system consists

of two primary components, the Recipient Report, and the Provider Report, and a data file containing de-identified client-level data elements. Data are submitted annually. The RWHAP statute specifies the importance of recipient accountability and linking performance to budget. The RSR is used to ensure recipient compliance with the law, including evaluating the effectiveness of programs, monitoring recipient and provider performance, and informing annual reports to Congress. Information collected through the RSR is critical for HRSA, state and local grant recipients, and individual providers to assess the status of existing HIV-related service delivery systems, monitor trends in service utilization, evaluate the impact of data reporting, and identify areas of greatest need.

Likely Respondents: RWHAP grant recipients, as well as their subawarded service providers, funded under RWHAP Parts A, B, C, and D.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Recipient Report	595	1	595	11	6,545
Provider Report	2,063	1	2,063	13	26,819
Client Report	1,532	1	1,532	113	173,116
Total	4,190		4,190		206,480

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–08610 Filed 4–22–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group; Reproduction, Andrology, and Gynecology Study Section.

Date: June 20, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 10 Center Drive, Room 10D39, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jagpreet Singh Nanda, Ph.D., Scientific Review Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institute of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892, (301) 451–4454, *jagpreet.nanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08632 Filed 4–22–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: May 21, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Rekha Dhanwani, Ph.D., Scientific Review Program, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious

Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9834, Rockville, MD 20852, (240) 627–3076, *rekha.dhanwani@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08635 Filed 4–22–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the *Eunice Kennedy Shriver* National Institute Of Child Health & Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group; Biobehavioral and Behavioral Sciences Study Section.

Date: June 18, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Chi-Tso Chiu, Ph.D., Scientific Review Branch, *Eunice Kennedy Shriver* National Institute of Child Health & Human Development, National Institute of Health, 6710B Rockledge Drive, Rm. 2127B, Bethesda, MD 20817, (301) 435–7486, *chiuc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08634 Filed 4–22–24; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute Environmental Health Sciences.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/*.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute Of Environmental Health Sciences, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute Environmental Health Sciences ESBSC June 23–25, 2024 Meeting.

Date: June 23–25, 2024.

Closed: June 23, 2024, 7:00 p.m. to 8:00 p.m.

Agenda: Discussion of BSC Reviews.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Open: June 24, 2024, 8:30 a.m. to 10:00 a.m.

Agenda: Meeting Overview and Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Open: June 24, 2024, 10:15 a.m. to 11:55 a.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 24, 2024, 12:00 p.m. to 12:45 p.m.

Agenda: 1:1 Sessions with Investigators.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 24, 2024, 12:45 p.m. to 1:45 p.m.

Agenda: Working Lunch.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Open: June 24, 2024, 1:45 p.m. to 3:25 p.m.

Agenda: Q&A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 24, 2024, 3:40 p.m. to 4:10 p.m.

Agenda: 1:1 Sessions with Investigators.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Open: June 24, 2024, 4:10 p.m. to 4:35 p.m.

Agenda: Q & A Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Open: June 25, 2024, 8:30 a.m. to 10:00 a.m.

Agenda: Poster Session.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 25, 2024, 10:15 a.m. to 11:15 a.m.

Agenda: Meeting with Fellows, Staff Scientists, Biologists, and Chemists.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 25, 2024, 11:15 a.m. to 11:45 a.m.

Agenda: Meeting with Core Director.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 25, 2024, 11:45 a.m. to 1:30 p.m.

Agenda: Working Lunch.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 25, 2024, 1:30 p.m. to 3:00 p.m.

Agenda: BSC Discussion.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: June 25, 2024, 3:15 p.m. to 3:45 p.m.

Agenda: Debriefing to NIEHS/DIR Leadership.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Contact Person: Darryl C. Zeldin, National Institute Environmental Health Sciences (NIEHS), 111 TW Alexander Drive, Research Triangle Park, NC 27709, 984–287–3641, *zeldin@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(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: April 17, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08587 Filed 4–22–24; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIEHS Videocast at the following link: *https://www.niehs.nih.gov/news/webcasts/index.cfm.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: June 4, 2024.

Open: 9:00 a.m. to 4:30 p.m.

Agenda: Discussion of Program Policies and Issues/Council Discussion.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Closed: 5:00 p.m. to 5:45 p.m.

Agenda: Review and Evaluate Grant Applications.

Place: National Institute Environmental Health Sciences (NIEHS), Rodbell Auditorium, 111 TW Alexander Drive, Research Triangle Park, NC 27709, (Hybrid Meeting).

Contact Person: David M Balshaw, Ph.D., Director, Division of Extramural Research and Training, National Institute of Environmental, Health Sciences, P.O. Box 12233, MD EC–27, Research Triangle Park, NC 27709–2233, 984–287–3234, *balshaw@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: April 17, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–08586 Filed 4–22–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0008]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Biographic Information (for Deferred Action)

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 (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension 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 June 24, 2024.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0008 in the body of the letter, the agency name and Docket ID USCIS–2005–0024. Comments must be submitted in English, or an English translation must be provided. Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2005–0024.

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: *http://www.regulations.gov* and enter USCIS–2005–0024 in the search box. Comments must be submitted in English, or an English translation must be provided. 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:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Biographic Information (for Deferred Action).

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–325A; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS uses Form G–325A to collect biographic information from individuals requesting either military deferred action or non-military deferred action (other than deferred action based on DACA, Violence Against Women Act, A–3, G–5, and T and V nonimmigrant visas).

(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 G–325A is 1,550 and the estimated hour burden per response is 2.15 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 3,875 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 $38,750.

Dated: April 17, 2024.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2024–08638 Filed 4–22–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6451–N–02]

Announcement of the Housing Counseling Federal Advisory Committee; Notice of Public Meeting

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice of Housing Counseling Federal Advisory Committee public meeting.

SUMMARY: This gives notice of a Housing Counseling Federal Advisory Committee (HCFAC) meeting and sets forth the proposed agenda. The HCFAC meeting will be held on Thursday, June 13, 2024. The meeting is open to the public and is accessible to individuals with disabilities.

DATES: The virtual meeting will be held on Thursday, June 13, 2024, starting at 1:00 p.m. Eastern Daylight Time (EDT), via ZOOM.

FOR FURTHER INFORMATION CONTACT: Virginia F. Holman, Housing Program Technical Specialist, Office of Housing

Counseling, U.S. Department of Housing and Urban Development, 600 East Broad Street, Richmond, VA 23219; telephone number 540–894–7790 (this is not a toll-free number); email *virginia.f.holman@hud.gov.*

HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Individuals may also email *HCFACCommittee@hud.gov.*

SUPPLEMENTARY INFORMATION: HUD is convening the virtual meeting of the HCFAC on Thursday June 13, 2024, from 1:00 p.m. to 4:30 p.m. EDT. The meeting will be held via ZOOM. This meeting notice is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. 1009(a)(2).

Draft Agenda—Housing Counseling Federal Advisory Committee Meeting

Thursday, June 13, 2024

The Housing Counselors' Role in Educating Consumers About Real Estate Commissions & Augmenting the Delivery of Housing Counseling in Tribal Communities.

I. Welcome
II. Presentations and HCFAC Member Discussion
III. Public Comment
IV. Next Steps
V. Adjourn

Registration

The public is invited to attend this half-day (3.5 hours) virtual meeting, using ZOOM. Advance registration is required to attend. To register, please visit *https://us06web.zoom.us/webinar/register/WN_9PkLZ88JRa2wcTgyXjeRcA#/registration* to complete your registration. If you have any questions about registration, please email *HCFACCommittee@ajantaconsulting.com.* After submitting the registration form, you will receive registration confirmation with the meeting link and passcode needed to attend. Closed captioning will be available during the ZOOM meeting.

Comments

Members of the public will have an opportunity to provide oral and written comments relative to agenda topics for the HCFAC's consideration. Your registration confirmation will also explain the process for speaking. Available time for public comments will be limited to ensure pertinent HCFAC business is completed. The amount of time allotted to each person will be limited to two minutes and will be allocated on a first-come first-served basis by HUD. Written comments can be provided on the registration form no later than June 12, 2024. Please note, written comments submitted will not be read during the meeting. The HCFAC will not respond to individual written or oral statements during the meeting; but it will take all public comments into account in its deliberations.

Meeting Records

Records and documents discussed during the meeting as well as other information about the work of the HCFAC, will be available for public viewing as they become available on hud.gov at: *https://www.hud.gov/program_offices/housing/sfh/hcc/housing_counseling;* and at *https://www.facadatabase.gov/FACA/s/login/?ec=302&inst=3d&startURL=%2FFACA%2Fapex%2FFACAPublicCommittee%3Fid%3Da10t0000001gzvQAAQ.*

Information on the Committee is also available on HUD Exchange at *https://www.hudexchange.info/programs/housing-counseling/federal-advisory-committee.*

Julia R. Gordon,

Assistant Secretary for Housing, FHA Commissioner.

[FR Doc. 2024–08647 Filed 4–22–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[245A2100DD/AAKC001030/A0A501010.999900]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment Between the Suquamish Indian Tribe of the Port Madison Reservation and the State of Washington

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Seventh Amendment to the Tribal-State Compact for Class III Gaming between the Suquamish Indian Tribe of the Port Madison Reservation and the State of Washington, titled Memorandum of Incorporation of Most Favored Nation Amendments to the Tribal State Compact for Class III Gaming between the Suquamish Tribe and the State of Washington.

DATES: The Amendment takes effect on April 23, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, *IndianGaming@bia.gov;* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment authorizes the Tribe to offer Sports Pools in accordance with State Law and specific procedures outlined in the Amendment.

The Amendment is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2024–08661 Filed 4–22–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–37814; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before April 13, 2024, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by May 8, 2024.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW,

MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before April 12, 2024. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State or Tribal Historic Preservation Officers.

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

KANSAS

Labette County

Oakwood Cemetery, 300 South Leawood Drive, Parsons, SG100010344

MASSACHUSETTS

Worcester County

J.R. Torrey Razor Co. and J. R. Torrey & Co. Manufacturing Facility, 128 Chandler Street, Worcester, SG100010339

NEW YORK

Monroe County

Ellwanger & Barry-Highland Park Historic District, Portions of Linden, Crawford, Mulberry, Meigs, Rockingham and South Goodman Streets; Gregory Hill Road, Mt. Vernon Avenue, Greenview Drive, & Highland Parkway, Rochester, SG100010347

New York County

Three Arts Club, 340 West 85th Street, New York, SG100010346

Onondaga County

Kemp & Burpee-Brown-Lipe Company Buildings, (Industrial Resources in the City of Syracuse, Onondaga County, NY MPS), 1117 W Fayette St and 200–206 S. Geddes St, Syracuse, MP100010352

Rensselaer County

Fitzgerald Brothers Brewing Company Bottling Works, 500 River Street, Troy, SG100010345

OREGON

Jackson County

Malmgren Garage, 111 Talent Avenue, Talent, SG100010337

VIRGINIA

Petersburg INDEPENDENT CITY

William R. McKenney Memorial Building, 137 South Sycamore Street, Petersburg, SG100010351

Virginia Beach INDEPENDENT CITY

Seatack Historic District

Ackiss Ave, Americus Ave, Beautiful St, Bells Rd, Birdneck Rd, Brooklyn Ave, Burford Ave, Butts Ln, Carver Ave, Frazee Ln. Hope Ave. Hughes Ave, Longstreet Ave. Loretta Ln, Norfolk Ave, Old Virginia Beach Rd. Olds Ln, Owls Creek Ln, Sea St, Summerville Ct, Virginia Beach, SG100010348

WASHINGTON

Spokane County

American Legion Cenotaph—Riverside Park Cemetery, 508 N Government Way, Spokane vicinity, SG100010340

Wahkiakum County

Hansen, Julia Butler, House, 35 Butler Street, Cathlamet, SG100010342

WISCONSIN

Milwaukee County

Hotel Schroeder, 509 West Wisconsin, Milwaukee, SG100010338

A request to move has been received for the following resource(s):

WASHINGTON

King County

Pacific Coast Company House No. 75, N of Renton at 7210 138th St. SE, Renton vicinity, MV79002534

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2024–08607 Filed 4–22–24; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain High-Strength Aluminum or Aluminum Alloy-Coated Steel, and Automotive Products and Automobiles Containing Same,* DN 3738*;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of ArcelorMittal on April 17, 2024. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain high-strength aluminum or aluminum alloy-coated steel, and automotive products and automobiles containing same. The complaint names as respondents: VinFast Auto Ltd. of Vietnam; VinFast Auto, LLC of Los Angeles, CA; VinFast USA Distribution, LLC of Los Angeles, CA; Vingroup USA, LLC of Los Angeles, CA; and VinFast Trading and Production JSC of Vietnam. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this

investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3738'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures).[1]

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. Government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: April 18, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–08651 Filed 4–22–24; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1265 (Enforcement)]

Certain Fitness Devices, Streaming Components Thereof, and Systems Containing Same; Notice of Commission Determination Not To Review an Initial Determination Terminating the Enforcement Proceeding Based on Settlement; Termination of the Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 11) of the presiding Chief Administrative Law Judge (''CALJ'') terminating the enforcement proceeding based on settlement. The enforcement proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On May 19, 2021, the Commission instituted the underlying investigation based on a complaint filed on behalf of complainants DISH DBS Corporation of Englewood, Colorado; DISH Technologies L.L.C. of Englewood, Colorado; and Sling TV L.L.C. of Englewood, Colorado (collectively, ''DISH''). 86 FR 27106, 27106–07 (May 19, 2021). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain fitness devices, streaming components thereof, and systems containing the same by reason of infringement of certain claims of U.S. Patent Nos. 9,407,564 (''the '564

patent''); 10,469,554 (''the '554 patent''); 10,469,555 (''the '555 patent''); 10,757,156 (''the '156 patent''); and 10,951,680 (''the '680 patent''). *Id.* The complaint further alleged that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents iFIT Inc., f/k/a ICON Health & Fitness, Inc. of Logan, Utah; FreeMotion Fitness, Inc. of Logan, Utah; NordicTrack, Inc. of Logan, Utah (together with iFIT Inc. and FreeMotion Fitness, Inc., ''iFit''); Peloton Interactive, Inc. of New York, New York (''Peloton''); lululemon athletica inc. of Vancouver, Canada; and Curiouser Products Inc. d/b/a MIRROR of New York, New York (together with lululemon athletica inc., ''MIRROR,'' and together with the other respondents, ''Respondents''). *Id.;* Order No. 14 (Nov. 4, 2021), *unreviewed by* Comm'n Notice (Dec. 6, 2021), 86 FR 70532 (Dec. 10, 2021). The Office of Unfair Import Investigations (''OUII'') participated in the investigation. 86 FR at 27106–07.

On March 8, 2023, the Commission issued its final determination, finding respondents Peloton and iFit in violation of section 337 as to the asserted claims of the '156, '554, and '555 patents, but not as to the asserted claims of the '564 patent. *See* 88 FR 15736 (Mar. 14, 2023). The investigation had terminated as to the asserted claims of the '680 patent prior to the issuance of the final initial determination, Order No. 21 (Mar. 3, 2022), *unreviewed by* Comm'n Notice (Mar. 23, 2022), and the final determination granted an unopposed motion to terminate as to MIRROR. *See* 88 FR at 15736. As a remedy, the Commission issued a limited exclusion order and cease and desist orders directed to Peloton and iFit. *Id.*

On May 5, 2023, the Commission modified the remedial orders in certain respects. *See* 88 FR 30158 (May 10, 2023). On June 1, 2023, the Commission rescinded the remedial orders directed to Peloton. *See* 88 FR 37274 (June 7, 2023).

On October 17, 2023, the Commission instituted an enforcement proceeding under Commission Rule 210.75 (19 CFR 210.75) to investigate alleged violations of the remedial orders by iFit. 88 FR 71603 (Oct. 17, 2023). In addition to DISH and iFit, OUII was also named as a party to the enforcement proceeding. *See id.*

On March 8, 2024, DISH and iFIT filed a joint motion requesting termination of the enforcement proceeding based on a settlement agreement. On March 18, 2024, OUII filed a response supporting the motion. No other responses were received in response to the motion. Separately, DISH filed a petition with the Commission requesting that the Commission rescind the remedial orders issued in the underlying investigation based on the settlement.

On March 19, 2024, the CALJ issued the subject ID (Order No. 11) granting the motion. The ID found that the joint motion complies with Commission Rule 210.21(b)(1), 19 CFR 210.21(b)(1). Furthermore, in accordance with Commission Rule 210.50(b)(2), 19 CFR 210.50(b)(2), the ID found ''no evidence that terminating this enforcement proceeding on the basis of settlement would adversely affect'' the public interest. *See* Order No. 11 at 3.

No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. The enforcement proceeding in this investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on April 18, 2024.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 18, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–08640 Filed 4–22–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 001–2024]

Privacy Act of 1974; Systems of Records

AGENCY: Environment and Natural Resources Division, United States Department of Justice.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974 and Office of Management and Budget (OMB) Circular No. A–108, notice is hereby given that the Environment and Natural Resources Division (hereinafter ''ENRD'' or ''Division''), a component within the United States Department of Justice (DOJ or Department), proposes to modify a system of records last published in full on February 23, 2000, titled ''Environment and Natural Resources Division Case and Related Files System,'' (JUSTICE/ENRD–003).

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is applicable upon publication, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by May 23, 2024.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments by mail to the United States Department of Justice, Office of Privacy and Civil Liberties, ATTN: Privacy Analyst, 145 N St. NW, Suite 8W.300, Washington, DC 20530; by facsimile at 202–307–0693; or by email at *privacy.compliance@usdoj.gov.* To ensure proper handling, please reference the above CPCLO Order No. on your correspondence.

FOR FURTHER INFORMATION CONTACT: Charles Smiroldo, FOIA Coordinator and Public Liaison, Department of Justice, Environment and Natural Resources Division Law and Policy Section, 950 Pennsylvania Avenue NW, Washington, DC 20530–0001 Telephone: (202) 514–0424.

SUPPLEMENTARY INFORMATION: Pursuant to updated OMB Guidance, ENRD has made administrative edits to the order and titles of sections in the notice. The Division also proposes these modifications to incorporate substantial developments made to the ENRD Justice Consolidated Office Network (ENRD JCON) information system, where the Division's ''Case and Related Files System'' is maintained, in addition to various applications which maintain additional categories of information subject to the Privacy Act. Specifically, the Division will modify the system of records by renaming it, ''Environment and Natural Resources Division Administrative and Case Related Files'' (JUSTICE/ENRD–003); updating the ''System Manager(s)'' and ''Addresses'' section to reflect administrative changes; revising the categories of records covered by adding additional information maintained by applications housed on ENRD JCON; adding new routine uses for the new categories of records maintained on ENRD JCON (primarily relating to the electronic management and handling of case files during investigation and litigation, human capital, transit subsidy and financial reporting information, and public access to the records pursuant to Federal statutes or regulations); deleting and revising routine uses to provide clarity and additional specificity; revising the categories of records and purpose sections to reflect changes made to the system of records that

enable Division attorneys, managers and support personnel with the ability to collect, organize, analyze and disseminate information more efficiently. Because of the number of changes made and for public convenience, the modified system of records notice has been printed below in full, replacing the previous notice in its entirety.

ENRD continues to assert the same Privacy Act (j) and (k) exemptions as previously published in 28 CFR 16.92.

As stated above, the purpose of the modified notice is to incorporate the changes and developments to the ENRD JCON information system, a standalone major system residing on the DOJ Justice Consolidated Office Network (JCON) general support system platform, which includes hybrid cloud and on-premises hosting environments. The system interconnects with various applications designed to facilitate ENRD litigation support, and to manage administrative processes. The purpose for modifying the Privacy Act System of Records Notice is to assist with the facilitation of ENRD's litigation mission, and the Division's need to collect and maintain information pertaining to civil and criminal enforcement investigations, actions, and defensive work on behalf of the United States Government. Specifically, collecting and maintaining the records will support ENRD in reviewing documents for relevance and privilege claims, tracking use of documentary evidence in litigation, preparing witness kits/binders for depositions and hearings, determining and organizing the facts about the case, and selecting exhibits for trial. The records will also be used to support ENRD's administrative functions.

Additional modifications to the system of records have been made to incorporate OMB guidance, technological advancements, and update existing routine uses and propose new routine uses. Pursuant to OMB Circular No. A–108, various sections were rearranged, and various section titles were edited. ENRD moves the System Manager(s) section in the system of records notice, as well as edited Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System: Storage, Retrievability, Safeguards, and Retention and Disposal to the following section titles: Policies and Practices for Storage of Records; Policies and Practices for Retrieval of Records; Policies and Practices for Retrieval of Records; Policies and Practices for Retention and Disposal of Records; and Administrative, Technical, and Physical Safeguards. Technological advancements, such as the ability to store records in the cloud and creation of stronger authentication methods, and institutional changes led the ENRD to modify and update the Policies and Practices for Storage of Records, Policies and Practices for Retrieval of Records, Administrative, Technical, and Physical Safeguards, System Location, and System Manager(s), and Addresses sections.

Previously routine uses have been consolidated and updated with language consistent with other Department routine uses. ENRD also has included new routine uses, including model routine uses that are included in all DOJ SORNs. The model routine uses permit disclosure to: to a former employee of the Department for purposes of responding to an official inquiry by a Federal, State, or local government entity or professional licensing authority, in accordance with applicable Department regulations; facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility; communication with licensing agencies or associations which require information concerning the suitability or eligibility of an individual for a license or permit; communication with contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records; communication with designated officers and employees of State, local, territorial, or Tribal law enforcement or detention agencies in connection with the hiring or continued employment of an employee or contractor, where the employee or contractor would occupy or occupies a position of public trust as a law enforcement officer or detention officer having direct contact with the public or with prisoners or detainees, to the extent that the information is relevant and necessary to the recipient agency's decision; communication with any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of ENRD and meeting related reporting requirements; and communication with any entities or individuals under such circumstances and procedures as are mandated by Federal statute or treaty. ENRD also proposes two new routine uses (x) and (y) to permit disclosure of information related to caring for a live animal or plant that has been seized as a result of an investigation, and to the public, where required, for purposes of publishing proposed consent decrees, settlements, or comments, respectively.

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and Congress on this new system of records.

Dated: March 28, 2024.

Peter A. Winn,

Acting Privacy and Civil Liberties Officer, United States Department of Justice.

JUSTICE/ENRD–003

SYSTEM NAME AND NUMBER:

''Environment and Natural Resources Division Administrative and Case Related Files,'' (JUSTICE/ENRD–003).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located in hybrid cloud and on-premise hosting environments, and may be retained in the Central Office, Field Offices/Locations, Offsite Storage Facilities, or Federal Records Center. Primary contact information may be found on the ENRD's website at *https://www.justice.gov/enrd.*

SYSTEM MANAGER(S):

The System Manager is the Assistant Director, Office of Information Technology, in coordination with the Office of Administrative Services' Records Management Unit.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority to establish and maintain this system is contained in 5 U.S.C. 301 and 44 U.S.C. 3101, which authorize the Attorney General to create and maintain Federal records of agency activities, in addition to 28 U.S.C. 514–19; 42 U.S.C. 7413(g); 5 U.S.C. 552; 42 U.S.C. 6973(d); 42 U.S.C. 9622(d)(2); 42 U.S.C. 9622(i); 28 CFR Part O, subpart L; 28 CFR 50.7; and 28 CFR 16.41.

PURPOSE(S) OF THE SYSTEM:

Case records are maintained to litigate or otherwise resolve civil or criminal cases or matters handled by ENRD. The automated case tracking is maintained to manage and evaluate the Division's litigation and related activities, which includes reviewing documents for relevance and privilege claims, tracking use of documentary evidence in litigation, preparing witness kits/binders for depositions and hearings, determining and organizing the facts about the case, and selecting exhibits for

trial. Internal case management, financial reporting, FOIA request tracking, and the Division's personnel records are also maintained in order to fulfill ENRD's legal and administrative functions.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals covered by this system include: (a) individuals being investigated in anticipation of civil or criminal suits; (b) individuals involved in civil or criminal suits; (c) defense or plaintiff's counsel(s); (d) information sources; (e) individuals relevant to the development of civil or criminal suits, including expert and other witnesses; (f) individual plaintiffs or defendants; (g) members of the public who contact the Division; and (h) attorneys, paralegals, and other employees of the Division directly involved in these cases or personnel related matters.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in this system include information relating to: (1) litigation and related activities by the Division, including, but not limited to, the protection, use and development of natural resources and public lands, wildlife protection, Indian rights and claims, cleanup of hazardous waste sites, acquisition of private property for Federal use, prosecution of environmental crimes, enforcement of environmental laws, and defense of environmental challenges to government programs and activities. The case files contain court records (such as briefs, motions, and orders), inter-agency and intra-agency correspondence, legal research, and other related documents. These records may include civil investigatory and/or criminal law enforcement information and information classified pursuant to Executive order to protect national security interests. (2) Summary information of these cases or matters (such as names of principal parties or subjects, court docket numbers, status, and attorney assignments) is maintained in an automated Case Management and Time Reporting software application. (3) A timekeeping function for attorneys, paralegals, and other employees of the Division provides data used in: civil and criminal enforcement investigations, actions and litigation; documentary evidence including relevance and privilege claims; witness kits/binders for depositions and hearings; trial exhibits and other litigation support documentation; financial reporting documentation; ENRD personnel records; correspondence, comments, and requests for members of the public; and internal case management records.

RECORD SOURCE CATEGORIES:

Sources of information contained in this system include, but are not limited to: investigative reports of client agencies of the Department of Justice; discovery materials; non-Department of Justice forensic reports; statements of witnesses and parties; verbatim transcripts of depositions and court proceedings; data, public reports, memoranda and reports from the court and agencies thereof; and Division Attorneys, Department of Justice attorneys, investigators, staff, and legal assistants.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(a) Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate Federal, State, local, territorial, Tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law;

(b) To any person or entity that the ENRD has reason to believe possesses information regarding a matter within the jurisdiction of the ENRD, to the extent deemed to be necessary by the ENRD in order to elicit such information or cooperation from the recipient for use in the performance of an authorized activity;

(c) A record relating to a case or matter may be disseminated in a Federal, State, local, or Tribal administrative or regulatory proceeding or hearing in accordance with the procedures governing such proceeding or hearing;

(d) To an actual or potential party to litigation or the party's authorized representative, or to a third party neutral, for the purpose of negotiation or discussion of such matters as settlement, plea bargaining, or formal or informal discovery proceedings;

(e) A record relating to a case or matter that has been referred by an agency for investigation, civil or criminal action, enforcement or defense, or that involves a case or matter within the jurisdiction of an agency, may be disseminated to such agency to notify it of the status of the case or matter, or of any decision or determination that has been made, or to make such other inquiries and reports as are necessary during the processing of the case or matter;

(f) A record relating to a case or matter may be disseminated to a foreign country, through the United States Department of State or directly to the representative of such country, pursuant to an international treaty or convention entered into and ratified by the United States or pursuant to an executive agreement;

(g) A record may be disseminated to a foreign country, through the Department of Justice Civil Division, United States Department of State, or directly to the representative of such country, to the extent necessary to assist such country in general crime prevention, the pursuit of civil or criminal judicial actions or general civil regulatory or administrative actions, or to provide investigative leads to such country, or assist in the location and/or returning of witnesses and other evidence;

(h) In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body, when the Department of Justice determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding;

(i) To the news media and the public, including disclosures pursuant to 28 CFR 50.2, unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy;

(j) To appropriate officials and employees of a Federal agency or entity that requires information relevant to a decision concerning the hiring, appointment, or retention of an employee; the assignment, detail, or deployment of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract, or the issuance of a grant or benefit;

(k) Pursuant to subsection b(12) of the Privacy Act, records relating to an individual who owes an overdue debt to the United States may be disseminated

to a Federal agency which employs the individual; a consumer reporting agency; a Federal, State, local or foreign agency; or the Internal Revenue Service (IRS);

(l) To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record;

(m) To the National Archives and Records Administration for purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906;

(n) To complainants and/or victims to the extent necessary to provide such persons with information and explanations concerning the progress and/or results of the investigation or case arising from the matters of which they complained and/or of which they were a victim;

(o) Timekeeping records may be disclosed to opposing parties and to courts in litigation regarding litigation costs;

(p) To a former employee of the Department for purposes of: responding to an official inquiry by a Federal, State, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility;

(q) To appropriate agencies, entities, and persons when (1) the Department suspects or has confirmed that there has been a breach of the system of records; (2) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm;

(r) To another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(s) To Federal, State, local, territorial, Tribal, foreign, or international licensing agencies or associations which require information concerning the suitability or eligibility of an individual for a license or permit;

(t) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records;

(u) To designated officers and employees of state, local, territorial, or tribal law enforcement or detention agencies in connection with the hiring or continued employment of an employee or contractor, where the employee or contractor would occupy or occupies a position of public trust as a law enforcement officer or detention officer having direct contact with the public or with prisoners or detainees, to the extent that the information is relevant and necessary to the recipient agency's decision;

(v) To any agency, organization, or individual for the purpose of performing authorized audit or oversight operations of ENRD and meeting related reporting requirements;

(w) To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty;

(x) In a matter under investigation or in litigation, a record, or facts derived from it, may be disclosed to an organization or person who is taking a live animal or plant into their care for the purpose of preventing harm to that animal or plant.

(y) To the public, for the purposes of publishing proposed consent decrees, settlements, or comments thereon, as may be required by statute, regulation, or Department policy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All information, except that specified in this paragraph, is recorded on computer files or basic paper/cardboard material that is stored in file folders, file cabinets, shelves, or safes. Some material is recorded and stored on other data processing storage forms located in file rooms and offsite facilities.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system are retrieved by the name of the individual, employee identification number, tax identification number, case number, case name, complainant/court docket number, and in limited circumstances Social Security number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with the Federal Records Act, DOJ's Office of Records Management Policy (ORMP), and consistent with NARA standards, ENRD ensures that all applications hosted on the ENRD JCON system are in compliance with appropriate retention schedules to manage the use, maintenance, retention and disposition of all DOJ records created and captured. Records are maintained in paper and electronic format, and retentions periods for these records, which include case files, range from approximately 2 years to 100 years after the case closure date. Temporary records are destroyed at the end of the retention period, and permanent records are transferred to the custody of NARA.

To ensure NARA and OMB electronic records compliance, ENRD is modernizing its information intake efforts. As part of this process, legacy hard copy records are in the process of being converted to electronic files for storage/use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records maintained in the ENRD JCON system are both confidential and non-confidential and located in file cabinets, safes and file rooms as well as hybrid cloud and on-premises hosting environments, and may be retained in the Central Office, Field Offices/ Locations, Offsite Storage Facilities, or Federal Records Center. Records are also located in litigation support contract document centers and offsite storage locations. Confidential records are in locked file drawers, safes, and secured file rooms. Offices are secured by either Federal Protective Service or private building guards. Electronic records retrievable by Division personnel trained to access existing ENRD software applications or successor applications, within various ENRD offices, are password protected and require access privileges to ENRD JCON.

RECORD ACCESS PROCEDURES:

All requests for access to records must be in writing and should be addressed to the Department of Justice, Environmental and Natural Resources Division, Law and Policy Section, 950 Pennsylvania Avenue NW, Washington, DC 20530 ATTN: FOIA/Privacy Act Coordinator. The envelope and letter

should be clearly marked ''Privacy Act Access Request.'' The request must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. The request must include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury. Some information may be exempt from the access provisions as described in the ''EXEMPTIONS PROMULGATED FOR THE SYSTEM'' paragraph, below. An individual who is the subject of a record in this system of records may access those records that are not exempt from access. A determination whether a record may be accessed will be made at the time a request is received.

Although no specific form is required, you may obtain forms for this purpose from the FOIA/Privacy Act Mail Referral Unit, United States Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530, or on the Department of Justice website at *https://www.justice.gov/oip/submit-and-track-request-or-appeal.*

More information regarding the Department's procedures for accessing records in accordance with the Privacy Act can be found at 28 CFR part 16 Subpart D, ''Protection of Privacy and Access to Individual Records Under the Privacy Act of 1974.''

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records maintained in this system of records must direct their requests to the address indicated in the ''RECORD ACCESS PROCEDURES'' paragraph, above. All requests to contest or amend records must be in writing and the envelope and letter should be clearly marked ''Privacy Act Amendment Request.'' All requests must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record. Some information may be exempt from the amendment provisions as described in the ''EXEMPTIONS PROMULGATED FOR THE SYSTEM'' paragraph, below. An individual who is the subject of a record in this system of records may contest or amend those records that are not exempt. A determination of whether a record is exempt from the amendment provisions will be made after a request is received.

More information regarding the Department's procedures for amending or contesting records in accordance with the Privacy Act can be found at 28 CFR 16.46, ''Requests for Amendment or Correction of Records.''

NOTIFICATION PROCEDURES:

Individuals may be notified if a record in this system of records pertains to them when the individuals request information utilizing the same procedures as those identified in the ''RECORD ACCESS PROCEDURES'' paragraph, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Attorney General has promulgated rules to exempt those records in this system that pertain to the enforcement of criminal laws, that are investigatory materials compiled for law enforcement purposes, or that are classified secret by an Executive Order, from the following Privacy Act requirements: (1) The requirement under (c)(3) to make available to the individual named in the record an accounting of the circumstances under which records about the individual were disclosed; (2) the requirement under (e)(1) to maintain only such information about an individual that is relevant and necessary to accomplish a purpose of the agency; and (3) the requirement under (f) to establish agency procedures to respond to an individual's request for information about himself. The Attorney General also has promulgated a rule to exempt records in this system compiled for criminal enforcement purposes from these additional requirements: (1) The requirement under (c)(4) to inform any party or agency that received an individual's records about any subsequent corrections made to the record; (2) the requirement under (e)(2) to collect information to the greatest extent practicable directly from the individual when the information may result in adverse determinations about an individual's rights, benefits and privileges under Federal programs; (3) the requirement under (e)(3) to inform each individual from whom information is collected of the authority for the information the principal purposes for the information, the routine uses, and the effects, if any, of not providing the information; (4) the requirement under (e)(5) to maintain all records with such accuracy, relevance, timeliness and completeness as is reasonably necessary to assure fairness to the individual, (5) the requirement under (e)(8) to make reasonable efforts to serve notice on an individual when any record on the individual is made available to any person under compulsory legal process when that process becomes a matter of public record; and (6) the authority under (g) providing that individuals may bring a civil action against the agency for violations of the Privacy Act.

These rules have been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c) and (e), and have been published in the **Federal Register**.

HISTORY:

65 FR 8990 (February 23, 2000): Last published in full; 66 FR 8425 (January 31, 2001); 70 FR 61159 (October 10, 2005); 72 FR 3410 (January 25, 2007) (Rescinded by 82 FR 24147); 82 FR 24147 (May 25, 2017).

[FR Doc. 2024–07613 Filed 4–22–24; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2019–0009]

DEKRA Certification Inc.: Grant of Expansion of Recognition and Modification to the NRTL Program's List of Appropriate Test Standards

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

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the final decision to expand the scope of recognition of DEKRA Certification Inc., (DEKRA) as a Nationally Recognized Testing Laboratory (NRTL). Additionally, OSHA announces the final decision to add one test standard to the NRTL List of Appropriate Test Standards.

DATES: The expansion of the scope of recognition becomes effective on April 23, 2024.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999 or email *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone (202) 693–1911 or email *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of the Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of DEKRA Certification Inc., (DEKRA) as a

NRTL. DEKRA's expansion covers the addition of three test standards to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by the applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes applications by NRTLs or applicant organizations for initial recognition, as well as for expansion or renewal of recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides a preliminary finding. In the second notice, the agency provides the final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including DEKRA, which details that NRTL's scope of recognition. These pages are available from the OSHA website at *https://www.osha.gov/dts/otpca/nrtl/index.html.*

DEKRA submitted an application on December 24, 2021 (OSHA–2019–0009–0004), which requested the addition of twenty-two standards to the scope of recognition. DEKRA submitted an amended application, dated June 21, 2023 (OSHA–2019–0009–0003), which requested that OSHA consider three of the twenty-two standards separately. OSHA then moved forward with consideration only of the three standards requested in the June 21, 2023, amended application; it is still evaluating the initial application and will announce the preliminary decision on the remaining nineteen standards in a separate notice. OSHA staff performed a detailed analysis of the application packet for the three standards covered by the June 21, 2023, amended application, and other pertinent information. OSHA staff performed an on-site assessment of DEKRA's Netherlands facility on June 5–7, 2023, in which OSHA assessors found some nonconformances with the requirements of 29 CFR 1910.7. DEKRA has addressed these issues sufficiently, and OSHA staff preliminarily determined that OSHA should grant the June 21, 2023, amended application.

OSHA published the preliminary notice announcing DEKRA's expansion application in the **Federal Register** on March 1, 2024 (89 FR 15223). The agency requested comments by March 18, 2024, but it received no comments in response to this notice.

To obtain or review copies of all public documents pertaining to the DEKRA application, go to *http://www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor. Docket No. OSHA–2019–0009 contains all materials in the record concerning DEKRA's recognition. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

II. Final Decision and Order

OSHA staff examined DEKRA's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that DEKRA meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitations and conditions listed in this notice. OSHA, therefore, is proceeding with this final notice to grant DEKRA's expanded scope of recognition. OSHA limits the expansion of DEKRA's recognition to testing and certification of products for demonstration of conformance to the test standards listed below in table 1.

TABLE 1—TEST STANDARDS FOR INCLUSION IN DEKRA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 2202	DC Charging Equipment for Electric Vehicles.
UL 2251*	Plugs, Receptacles, and Couplers for Electric Vehicles.
UL 2594	Electric Vehicle Supply Equipment.

* Represents the standard that OSHA will add to the NRTL Program's List of Appropriate Test Standards.

In this notice, OSHA also announces the final decision to add one new test standard to the NRTL Program's List of Appropriate Test Standards. Table 2 below lists the standard that is new to the NRTL Program. OSHA has determined that this test standard is an appropriate test standard and will add it to the NRTL Program's List of Appropriate Test Standards.

TABLE 2—STANDARD OSHA WILL ADD TO THE NRTL PROGRAM'S LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
UL 2251	Plugs, Receptacles, and Couplers for Electric Vehicles.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 01–00–004, Chapter 2, Section VIII), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7,

DEKRA must abide by the following conditions of the recognition:

1. DEKRA must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as a NRTL, and provide details of the change(s);

2. DEKRA must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. DEKRA must continue to meet the requirements for recognition, including all previously published conditions on DEKRA's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of DEKRA as a NRTL, subject to the limitations and conditions specified above. OSHA also adds one test standard to the NRTL Program's List of Appropriate Test Standards.

III. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1910.7.

Signed at Washington, DC, on April 16, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–08599 Filed 4–22–24; 8:45 am]

BILLING CODE 4510–26–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99984; File No. SR–PEARL–2024–19]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Minor, Non-Substantive Edits to Rule 531, Reports and Market Data Products

April 17, 2024.

Pursuant to the provisions of 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 April 9, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to amend (1) make a non-substantive, clarifying change to a footnote in prior rule filings submitted to the U.S. Securities and Exchange Commission (''Commission'') for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) [4] to adopt the Liquidity Taker Event Report and Liquidity Taker Event Report—Resting Simple Orders; [5] and (2) make a non-substantive clarifying change to Exchange Rule 531, Reports and Market Data Products.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* 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: (1) make a non-substantive, clarifying change to a footnote in prior rule filings submitted to the Commission for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act [6] and Rule 19b–4(f)(6) [7] thereunder to adopt the Liquidity Taker Event Report and Liquidity Taker Event Report—Resting Simple Orders; and (2) make a non-substantive clarifying change to Exchange Rule 531, Reports and Market Data Products.

The Exchange offers two versions of the Liquidity Taker Event Report: (1) Liquidity Taker Event Report (referred to herein as the ''Simple Order Report''); and (2) Liquidity Taker Event Report—Resting Simple Orders (referred to herein as the ''Resting Simple Order Report'').[8] Each of the Reports are available for purchase by Exchange Members [9] on a voluntary basis. The Exchange's prior rule filings to adopt each Liquidity Taker Event Report were submitted to the Commission for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11] Each Liquidity Taker Event Report is described under Exchange Rules 531(a) and (c).[12]

In general, each Liquidity Taker Event Report is a daily report that provides a Member (''Recipient Member'') with its liquidity response time details for executions and contra-side responses of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange notes that its affiliate, MIAX Emerald, LLC (''MIAX Emerald''), submitted the first filing to adopt the Liquidity Taker Event Report—Simple Orders, pursuant to Section 19(b)(2) of the Act. 15 U.S.C. 78s(b)(2). *See* Securities Exchange Act Release Nos. 91356 (March 18, 2021), 86 FR 15759 (March 24, 2021) (SR–EMERALD–2021–09) (Notice of Filing of a Proposed Rule Change To Adopt Exchange Rule 531, Reports, To Provide for the New ''Liquidity Taker Event Report''); *and* 91787 (May 6, 2021), 86 FR 26111 (May 12, 2021) (SR–EMERALD–2021–09) (Order Approving Proposed Rule Change To Adopt Exchange Rule 531(a), Reports, To Provide for a New ''Liquidity Taker Event Report'').

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6).

[8] The Simple Order Report and Resting Simple Order Report are collectively referred to herein as the ''Reports.''

[9] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of the Exchange's 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.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] *See* Exchange Rules 531(a) and (c); *see also* Securities Exchange Act Release Nos. 92082 (June 1, 2021), 86 FR 30337 (June 7, 2021) (SR–PEARL–2021–25) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 531, Reports and Market Data Products, To Adopt the Liquidity Taker Event Report for Options Trading); *and* 96837 (February 8, 2023), 88 FR 9543 (February 14, 2023) (SR–PEARL–2023–01) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 531, Reports and Market Data Products, To Provide for the New ''Liquidity Taker Event Report— Resting Simple Orders'').

an order resting on the Book,[13] where that Recipient Member attempted to execute against such resting order [14] within a certain timeframe.[15] The content of each of the Reports is specific to the Recipient Member and each Liquidity Taker Event Report does not include any information related to any Member other than the Recipient Member.

Proposal To Amend a Footnote in Each of the Filings To Adopt the Reports (SR–PEARL–2021–25 and SR–PEARL–2023–01)

The Exchange proposes to make a clarifying change to one of the footnotes in each of the filings to adopt each Liquidity Taker Event Report. Each of the filings to adopt each Liquidity Taker Event Report contains a section that describes information in each report that corresponds to the Recipient Member. Each of the prior filings states that the ''following information would be included in the [Simple Order Report or Resting Simple Order Report] regarding response(s) sent by the Recipient Member: (A) Recipient Member identifier; (B) the time difference between the time the first response that executes against the resting order was received by the Exchange and the time of each response sent by the Recipient Member, regardless of whether it executed or not; (C) size and type of each response submitted by Recipient Member; and (D) response reference number, which is a unique reference number attached to the response by the Recipient Member.[16] Further, each of the filings includes a footnote at the end of romanette ''(B)'' in the paragraph described above, which states as follows:

For purposes of calculating this duration of time, the Exchange will use the time the resting order and the Recipient Member's response(s) is received by the Exchange's network, both of which would be before the order and response(s) would be received by the System. This time difference would be provided in nanoseconds.[17]

The Exchange proposes to clarify the above footnote. Specifically, the Exchange proposes to replace ''the resting order'' with ''the first response that executes against the resting order.'' Accordingly, with the proposed change, the referenced footnotes in each of the filings to adopt the Reports would read as follows:

For purposes of calculating this duration of time, the Exchange will use the time the first response that executes against the resting order and the Recipient Member's response(s) is received by the Exchange's network, both of which would be before the order and response(s) would be received by the System. This time difference would be provided in nanoseconds.

The purpose of the proposed change is to correct a non-substantive error in a footnote of each rule filing to adopt the Reports. The Exchange notes that the rule text in Exchange Rule 531 that describes each of the Reports was correctly adopted and does not require any change; only the footnote described above needs to be clarified. This change does not impact or alter the information provided to any Recipient Member.

Cleanup to Exchange Rule 531(c)

The Exchange proposes to make a non-substantive clarifying change to Exchange Rule 531, Reports and Market Data Products. Currently, Exchange Rule 531(c) provides the rule text for the Resting Simple Order Report. In particular, Exchange Rule 531(c) provides that ''[t]he Liquidity Taker Event Report-Resting Simple Orders is a daily report that provides a Member ('Recipient Member') with its liquidity response time details for executions against an order resting on the Simple Order Book, where that Recipient Member attempted to execute against such resting order within the timeframe specified under paragraph (2) below.'' The Exchange proposes to delete the words ''Simple Order'' when referring to the Book. The purpose of this proposed change is to provide consistency and clarity within the Rulebook as the defined term, the ''Book,'' refers to the Exchange's electronic book of buy and sell orders and quotes maintained by the System.[18]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5),[20] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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.

The Exchange believes that the proposed change to each of the footnotes described above for each Liquidity Taker Event Report protects investors and the public interest, as well as removes impediments to and perfects the mechanism of a free and open market and a national market system because the change is designed solely to correct non-substantive errors in prior filings, and none which have any impact on the Exchange's actual rule text for each of the Reports. This proposed change does not impact or alter the operation of Exchange Rule 531 regarding the Reports.

Similarly, the Exchange believes that the proposed change to delete the words ''Simple Order'' when referring to the Book in Exchange Rule 531(c) removes impediments to and perfects the mechanism of a free and open market and a national market system because the change is designed to provide consistency and clarity within the Rulebook as the defined term, the ''Book,'' refers to the Exchange's electronic book of buy and sell orders and quotes maintained by the System. This proposed change does not impact or alter the operation of Exchange Rule 531(c).

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, as amended.

The non-substantive corrections to the footnotes in prior filings to adopt each Liquidity Taker Event Report would not impact competition because such changes would not enhance or alter the Exchange's ability to compete, but rather, clarify a prior error which would reduce the potential for inadvertent investor confusion. Similarly, the proposed change to delete the words ''Simple Order'' when referring to the Book in Exchange Rule 531(c) would not impact competition because such change would not enhance or alter the Exchange's ability to compete, but rather, provide consistency and clarity within the Rulebook.

[13] The ''Book'' is the Exchange's electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[14] Only displayed orders are included in the Reports. The Exchange notes that it does not currently offer any non-displayed orders on its options trading platform.

[15] A complete description of each of the Reports can be found in the prior rule filings to adopt the Reports. *See supra* note 12.

[16] *See supra* note 12. For the Simple Order Report, *see* Exchange Rule 531(a)(1)(iii); for the Resting Simple Order Report, *see* Exchange Rule 531(c)(1)(iii).

[17] *See supra* note 12, 86 FR 30337, at 30339, footnote 20; *and* 88 FR 9543, at 9545, footnote 21.

[18] *See* Exchange Rule 100.

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

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 from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and Rule 19b–4(f)(6) thereunder.[22]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [23] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [24] 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 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange stated that the proposed changes to the footnotes in the filings to adopt each of the Reports would correct non-substantive errors in prior filings. The Exchange also stated that the proposed non-substantive, clarifying change to Exchange Rule 531 deleting the words ''Simple Order'' when referring to the Book would provide consistency and clarity within the Rulebook. For these reasons, and because the proposal raises no novel legal or regulatory issues, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[25]

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–19 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–2024–19. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–19 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08576 Filed 4–22–24; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35172; File No. 813–00410]

Hines Investment Management Holdings Limited Partnership and Hines Employee Access I LP

April 17, 2024.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the ''Act'') granting an exemption from all provisions of the Act, except sections 9, 17, 30, and 36 through 53, and the rules and regulations under the Act (the ''Rules and Regulations''). With respect to sections 17(a), (d), (e), (f), (g), and (j) of the Act, sections 30(a), (b), (e), and (h) of the Act and the Rules and Regulations and rule 38a–1 under the Act, applicants request a limited exemption as set forth in the application.

SUMMARY OF APPLICATION: Applicants request an order to exempt certain limited partnerships, limited liability companies, business trusts or other entities (''Funds'') formed for the benefit of eligible employees of Hines Investment Management Holdings Limited Partnership and its affiliates from certain provisions of the Act. Each Fund, and each series thereof with segregated assets and liabilities, will be an ''employees' securities company'' within the meaning of section 2(a)(13) of the Act.

APPLICANTS: Hines Investment Management Holdings Limited Partnership and Hines Employee Access Partners I LP.

FILING DATES: The application was filed on August 17, 2022 and amended on March 14, 2023, November 1, 2023, February 16, 2024 and April 1, 2024.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on May 13, 2024, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Christopher Clark, LeRonica Hill, Richard Heaton at *corporate.counsel@hines.com.*

FOR FURTHER INFORMATION CONTACT: Matthew Cook, Senior Counsel, or Marc Mehrespand, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' fourth amended and restated application, dated April 1, 2024, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system.

The SEC's EDGAR system may be searched at, at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08582 Filed 4–22–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99975; File No. SR–BOX–2024–11]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Permit the Listing and Trading of Options Series With Tuesday and Thursday Expirations for Options on iShares Russell 2000 ETF (IWM)

April 17, 2024.

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 April 12, 2024, BOX Exchange LLC (''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 Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BOX Rule 5050 (Series of Options Contracts Open for Trading) to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (IWM), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *https://rules.boxexchange.com/rulefilings.*

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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 BOX Rule 5050 (Series of Options Contracts Open for Trading) to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (IWM), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM. This is a competitive filing that is based on a proposal submitted by NASDAQ ISE, LLC (''ISE'') and approved by the Commission.[5]

Currently, Table 1 in IM–5050–6 specifies each symbol that qualifies as a Short Term Option Daily Expiration.[6] Today, Table 1 permits the listing and trading of Monday Short Term Option Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[7] The listing and trading of Tuesday and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (Order Approving SR–ISE–2024–06).

[6] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). *See* BOX IM–5050–6.

[7] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 in IM–5050–6 from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed pursuant to the Short Term Option Series Program. The Exchange notes that Cboe Exchange, Inc. (''Cboe'') began listing Tuesday and Thursday expirations in the Russell 2000 Index Weeklys® (''RUTW'') and Mini-Russell 2000 Index Weeklys® (''MRUT'') on January 8, 2024.

Thursday Short Term Option Daily Expirations would be subject to IM–5050–6.

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (SPY) and the INVESCO QQQ Trust℠, Series 1 (QQQ) may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[8] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Wednesday Short Term Option Expiration Date''). In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[9] The interval between strike prices for the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday IWM Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[10] IM–5050–1(b) provides that, notwithstanding any other provision regarding the interval of strike prices of series of options on Exchange-Traded Fund Shares in BOX Rule 5050, the interval of strike prices on options on IWM will be $1 or greater.[11] Further, IM–5050–6(b)(5) provides that the interval between strike prices on Short Term Option Series may be (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments in Related non-short Term Options and are in the Short Term Option Series Program; or (iii) $2.50 or greater where the strike price is above $150. Specifically, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to BOX Rule 100(a)(66),[12] with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[13] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[14] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well.

With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to standard option series, Short Term Option Daily Expirations may expire in the same week in which standard option series on the same class expire.[15] Further, as is the case today with other Tuesday and Thursday Short Term Option Daily Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on the same day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series on the same class expire.[16] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[17] in general, and 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

[8] *See* BOX IM–5050–6.

[9] Today, IWM may trade on Mondays and Wednesdays, in addition to Fridays, as is the case for all options series.

[10] See BOX IM–5050–6(b)(5).

[11] Options on SPY, iShares Core S&P 500 ETF (''IVV''), QQQ, IWM, and the SPDR Dow Jones Industrial Average ETF (''DIA'') are also subject to IM–5050–1(b) strike intervals.

[12] BOX Rule 100(a)(66) provides, ''The term 'Short Term Option Series' means a series in an option class that is approved for listing and trading on BOX in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Tuesday, Wednesday, Thursday, or Friday of the next business week, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday, respectively. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.''

[13] See BOX IM–5050–6(b)(3) and (4).

[14] See BOX IM–5050–6(b)(1).

[15] See BOX IM–5050–6(b)(2).

[16] Id.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. In particular, the Exchange believes that IWM Tuesday and Thursday Short Term Option Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Option Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure. In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Option Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. BOX currently lists SPY and QQQ Tuesday and Thursday Short Term Option Daily Expirations.[19]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similarly to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[20] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on the same day in which standard expiration options series, Monthly Options Series or Quarterly Options Series expire.[21] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which standard expiration options series, Monthly Options Series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Option Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday IWM Short Term Option Daily Expirations.

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. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to a filing submitted by ISE that was recently approved by the Commission.[22] Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Option Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Option Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange notes that Cboe began listing Tuesday and Thursday expirations in RUTW and MRUT on January 8, 2024.

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short Term Option Series with Tuesday and Thursday Short Term Option Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on BOX.[23]

Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[24] and Rule 19b–4(f)(6) thereunder.[25] 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[26] and subparagraph (f)(6) of Rule 19b–4 thereunder.[27]

A proposed rule change filed under Rule 19b–4(f)(6)[28] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[29] the Commission may 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 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive

[19] *See* BOX IM–5050–6(a).

[20] *See* BOX IM–5050–6(b)(2).

[21] *Id.*

[22] *See supra,* note 3.

[23] *See* BOX IM–5050–6(a).

[24] 15 U.S.C. 78s(b)(3)(A)(iii).

[25] 17 CFR 240.19b–4(f)(6).

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[28] 17 CFR 240.19b–4(f)(6).

[29] 17 CFR 240.19b–4(f)(6)(iii).

response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[30] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as its competitor exchanges, thus creating competition among Short Term Option Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[31]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–BOX–2024–11 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BOX–2024–11. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BOX–2024–11 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Vanessa A. Countryman,

Secretary.

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BILLING CODE 8011–01–P

[30] See supra note 5.

[31] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99979; File No. SR–CboeBZX–2024–029]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Options Series Program in Rule 19.6, Interpretation and Policy .05

April 17, 2024.

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 April 15, 2024, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend the Short Term Options Series Program in Rule 19.6, Interpretation and Policy .05. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 (Series of Options Contracts Open for Trading). Specifically, the Exchange proposes to expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (''IWM''), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM.

Currently, Table 1 in Rule 19.6, Interpretation and Policy .05(h), specifies each symbol that qualifies as a Short Term Option Daily Expiration.[5]

[5] The Exchange may open for trading on any Thursday or Friday that is a business day series of

Today, Table 1 permits the listing and trading of Monday Short Term Option Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[6] The listing and trading of Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 19.6, Interpretation and Policy .05.

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (''SPY'') and the INVESCO QQQ TrustSM, Series 1 (''QQQ'') may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[7] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Wednesday Short Term Option Expiration Date'').[8]

In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[9]

The interval between strike prices for the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday IWM Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[10] Specifically, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to Rule 19.6, Interpretation and Policy .05(h), with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[11] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[12] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well. With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to monthly option series, Short Term Option Daily Expirations expire in the same week in which monthly option series on the same class expire.[13] Further, as is the case today with other Tuesday and Thursday Short Term Option Daily Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[14] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below table sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2023 in the options industry.[15] The Exchange notes that during this time period all options exchanges mitigated weekly strike intervals.

options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). See Rule 19.6, Interpretation and Policy .05.

[6] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 Rule 19.6, Interpretation and Policy .05(h) from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed pursuant to the Short Term Option Series.

[7] *See* Rule 19.6, Interpretation and Policy .05(h).

[8] *Id.*

[9] Today, IWM may trade on Mondays and Wednesdays, in addition to Fridays, as is the case for all options series.

[10] *See* Rule 19.6, Interpretation and Policy .05(e).

[11] *See* Rule 19.6, Interpretation and Policy .05(a).

[12] *See* Rule 19.6, Interpretation and Policy .05(a).

[13] *See* Rule 19.6, Interpretation and Policy .05(b).

[14] *See* Rule 19.6, Interpretation and Policy .05(h).

[15] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	62.82
Weekly	17.22
LEAP	17.77
Quarterly	2.20

Similar to SPY and QQQ, the Exchange would limit the number of Short Term Option Daily Expirations for IWM to two expirations for Tuesday and Thursday expirations while expanding the Short Term Option Series Program to permit Tuesday, and Thursday expirations for IWM. Expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in IWM will account for the addition of 6.77% of strikes for IWM.[16] With respect to the impact to the Short Term Option Series Program on IWM overall, the impact would be a 20% increase in strikes.[17] With respect to the impact to the Short Term Options Series Program overall, the impact would be a 0.1% increase in strikes.[18] Members will continue to be able to expand hedging tools because all days of the week would be available to permit Members to tailor their investment and hedging needs more effectively in IWM.

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	35.13
Weekly	48.30
LEAP	12.87
Quarterly	3.70

Weeklies comprise 48.30% of the total volume of options contracts.[19] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants. The introduction of IWM Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure. In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. The Exchange currently lists SPY and QQQ Tuesday and Thursday Short Term Daily Expirations.[23]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similar to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[24] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on a business day in which monthly options series or Quarterly Options Series expire.[25] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange notes the proposed rule change is substantively

[16] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[17] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[18] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[19] This table sets forth industry volume. Weeklies comprise 48.30% of volume while only comprising 17.22% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] *See* Rule 19.6, Interpretation and Policy .05(h).

[24] *See* Rule 19.6, Interpretation and Policy .05(b).

[25] *See* Rule 19.6, Interpretation and Policy .05(h).

the same as a rule change proposed by ISE, which the Commission recently approved.[26]

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. Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on the Exchange.[27] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[28] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30] 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[31] and subparagraph (f)(6) of Rule 19b–4 thereunder.[32]

A proposed rule change filed under Rule 19b–4(f)(6)[33] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[34] the Commission may 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 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[35] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as its competitor exchanges, thus creating competition among Short Term Option Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[36]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–029 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–029. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number

[26] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

[27] *See* Rule 19.6, Interpretation and Policy .05(h).

[28] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 15 U.S.C. 78s(b)(3)(A)(iii).

[32] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6)(iii).

[35] *See supra* note 26.

[36] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

SR–CboeBZX–2024–029 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08572 Filed 4–22–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99982; File No. SR–PEARL–2024–18]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Equities Fee Schedule

April 17, 2024.

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 April 4, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal 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 *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* 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 the Fee Schedule to: (1) modify certain rebates and volume thresholds for the NBBO Setter Plus Program (referred to in this filing as the ''NBBO Program''); [3] (2) modify the NBBO Setter Additive Rebate under the NBBO Program; (3) establish a new NBBO First Joiner Additive Rebate under the NBBO Program; and (4) establish a new Step-Up Rebate. The Exchange initially filed proposal on March 28, 2024 (SR–PEARL–2024–16). On April 4, 2024, the Exchange withdrew SR–PEARL–2024–16 and refiled this proposal.

Background of the NBBO Program

In general, the NBBO Program provides enhanced rebates for Equity Members [4] that add displayed liquidity (''Added Displayed Volume'') in securities priced at or above $1.00 per share in all Tapes based on increasing volume thresholds and increasing market quality levels (described below), and provides an additive rebate [5] applied to orders that set the NBB or NBO [6] upon entry.[7] The NBBO Program was implemented beginning September 1, 2023 and subsequently amended when the Exchange adopted two additional tiers of rebates, effective January 1, 2024.[8] The NBBO Program was further amended when the Exchange adopted an alternative method for Equity Members to achieve the enhanced rebate for Tier 5, Level C, effective March 1, 2024 (described below).[9]

Pursuant to the NBBO Setter Plus Table in Section 1)c) of the Fee Schedule, the NBBO Program provides six volume tiers enhanced by three market quality levels to provide increasing rebates in this segment. The six volume tiers are achievable by greater volume from the best of three alternative methods. The three market quality levels are achievable by greater NBBO participation in a minimum number of specific securities (described below).

MIAX Pearl Equities first determines the applicable NBBO Program tier based on three different volume calculation methods. The three volume-based methods to determine the Equity Member's tier for purposes of the NBBO Program are calculated in parallel in each month, and each Equity Member receives the highest tier achieved from any of the three methods each month. All three volume calculation methods are based on an Equity Member's respective ADAV,[10] NBBO Set Volume, or ADV, each as a percent of industry TCV [11] as the denominator.

Under volume calculation Method 1, the Exchange provides tiered rebates based on an Equity Member's ADAV as a percentage of TCV. An Equity Member qualifies for the base rebates in Tier 1 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.00% and less than 0.035% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 2 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.035% and less than 0.05% of TCV. An Equity Member qualifies for the enhanced

[37] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See, generally,* Fee Schedule, Section 1)c).

[4] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. *See* Exchange Rule 1901.

[5] *See* Fee Schedule, Section 1)c), NBBO Setter Additive Rebate.

[6] With respect to the trading of equity securities, the term ''NBB'' shall mean the national best bid, the term ''NBO'' shall mean the national best offer, and the term ''NBBO'' shall mean the national best bid and offer. *See* Exchange Rule 1901.

[7] *See supra* note 3.

[8] *See* Securities Exchange Act Release Nos. 98472 (September 21, 2023), 88 FR 66533 (September 27, 2023) (SR–PEARL–2023–45) *and* 99318 (January 11, 2024), 89 FR 3488 (January 18, 2024) (SR–PEARL–2023–73).

[9] *See* Securities Exchange Act Release No. 99695 (March 8, 2024), 89 FR 18694 (March, 14, 2024) (SR–PEARL–2024–11).

[10] ''ADAV'' means average daily added volume calculated as the number of shares added per day and ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day. ADAV and ADV are calculated on a monthly basis. ''NBBO Set Volume'' means the ADAV in all securities of an Equity Member that sets the NBB or NBO on MIAX Pearl Equities. The Exchange excludes from its calculation of ADAV, ADV, and NBBO Set Volume shares added or removed on any day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours, on any day with a scheduled early market close, and on the ''Russell Reconstitution Day'' (typically the last Friday in June). Routed shares are not included in the ADAV or ADV calculation. *See* the Definitions section of the Fee Schedule.

[11] ''TCV'' means total consolidated volume calculated as the volume in shares reported by all exchanges and reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply. The Exchange excludes from its calculation of TCV volume on any given day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours, on any day with a scheduled early market close, and on the ''Russell Reconstitution Day'' (typically the last Friday in June). *See id.*

rebates in Tier 3 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.05% and less than 0.08% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 4 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.08% and less than 0.25% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 5 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.25% and less than 0.40% of TCV. Finally, an Equity Member qualifies for the enhanced rebates in Tier 6 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.40% of TCV.

Under volume calculation Method 2, the Exchange provides tiered rebates based on an Equity Member's NBBO Set Volume as a percentage of TCV. Under volume calculation Method 2, an Equity Member qualifies for the base rebates in Tier 1 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.00% and less than 0.01% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 2 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.01% and less than 0.015% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 3 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.015% and less than 0.02% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 4 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.02% and less than 0.03% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 5 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.03% and less than 0.08% of TCV. Finally, an Equity Member qualifies for the enhanced rebates in Tier 6 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an NBBO Set Volume of at least 0.08% of TCV.

Under volume calculation Method 3, the Exchange provides tiered rebates based on an Equity Member's ADV as a percentage of TCV. An Equity Member qualifies for the base rebates in Tier 1 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 0.00% and less than 0.15% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 2 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 0.15% and less than 0.18% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 3 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 0.18% and less than 0.20% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 4 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 0.20% and less than 0.60% of TCV. An Equity Member qualifies for the enhanced rebates in Tier 5 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 0.60% and less than 1.00% of TCV. Finally, an Equity Member qualifies for the enhanced rebates in Tier 6 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADV of at least 1.00% of TCV.

After the volume calculation is performed to determine highest tier achieved by the Equity Member, the applicable rebate is calculated based on two different measurements based on the Equity Member's participation at the NBBO on the Exchange in certain securities (referenced below).

The Exchange provides one column of base rebates (referred to in the NBBO Setter Plus Table as ''Level A'') and two columns of enhanced rebates (referred to in the NBBO Setter Plus Table as ''Level B'' and ''Level C''),[12] depending on the Equity Member's Percent Time at NBBO [13] on MIAX Pearl Equities in a certain amount of specified securities (''Market Quality Securities'' or ''MQ Securities'').[14] The NBBO Setter Plus Table specifies the percentage of time that the Equity Member must be at the NBB or NBO on MIAX Pearl Equities in at least 200 symbols out of the full list of 1,000 MQ Securities (which symbols may vary from time to time based on market conditions). The list of MQ Securities is generally based on the top multi-listed 1,000 symbols by ADV across all U.S. securities exchanges. The list of MQ Securities is updated monthly by the Exchange and published on the Exchange's website.[15]

The base rebates (''Level A'') are as follows: ($0.00240) [16] per share in Tier 1; ($0.00290) per share in Tier 2; ($0.00300) per share in Tier 3; ($0.00310) per share in Tier 4; ($0.00345) per share in Tier 5; and ($0.00350) per share in Tier 6. Under Level B, the Exchange provides enhanced rebates for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes if the Equity Member's Percent Time at NBBO is at least 25% and less than 50% in at least 200 MQ Securities per trading day during the month. The Level B rebates are as follows: ($0.00250) per share in Tier 1; ($0.00295) per share in Tier 2; ($0.00305) per share in Tier 3; ($0.00315) per share in Tier 4; ($0.00350) per share in Tier 5; and ($0.00355) per share in Tier 6. Under Level C, the Exchange provides enhanced rebates for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes if the Equity Member's Percent Time at NBBO is at least 50% in at least 200 MQ Securities per trading day during the month. The Level C rebates are as follows:

[12] For the purpose of determining qualification for the rebates described in Level B and Level C of the Market Quality Tier columns in the NBBO Setter Plus Program, the Exchange will exclude from its calculation: (1) any trading day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours; (2) any day with a scheduled early market close; and (3) the ''Russell Reconstitution Day'' (typically the last Friday in June). *See* the Definitions section of the Fee Schedule.

[13] ''Percent Time at NBBO'' means the aggregate of the percentage of time during regular trading hours where a Member has a displayed order of at least one round lot at the national best bid (''NBB'') or national best offer (''NBO''). *See id.*

[14] ''Market Quality Securities'' or ''MQ Securities'' shall mean a list of securities designated as such, that are used for the purposes of qualifying for the rebates described in Level B and Level C of the Market Quality Tier columns in the NBBO Setter Plus Program. The universe of these securities will be determined by the Exchange and published on the Exchange's website. *See id.*

[15] *See e.g,* MIAX Pearl Equities Exchange—Market Quality Securities (MQ Securities) List, effective April 1 through April 30, 2024, *available at https://www.miaxglobal.com/markets/us-equities/pearl-equities/fees* (last visited April 4, 2024).

[16] Rebates are indicated by parentheses. *See* the General Notes section of the Fee Schedule.

($0.00260) per share in Tier 1; ($0.00300) per share in Tier 2; ($0.00310) per share in Tier 3; ($0.00320) per share in Tier 4; ($0.00355) per share in Tier 5; and ($0.00360) per share in Tier 6. As referenced above, Equity Members may also qualify for the Tier 5, Level C enhanced rebate via an alternative method by satisfying the following three requirements in the relevant month: (1) Midpoint ADAV [17] of at least 2,500,000 shares; (2) Displayed ADAV of at least 10,000,000 shares; and (3) Percent Time at the NBB or NBO of at least 50% in 200 or more symbols from the list of MQ Securities.[18]

The Exchange also offers an NBBO Setter Additive Rebate, which is an additive rebate of ($0.0003) per share for executions of orders in securities priced at or above $1.00 per share that set the NBB or NBO on MIAX Pearl Equities with a minimum size of a round lot.[19]

Proposal To Amend Certain Volume Thresholds and Rebates for the NBBO Program

The Exchange proposes to amend the NBBO Setter Plus Table in Section 1)c) of the Fee Schedule to: (1) amend the volume threshold requirements for Tiers 4 and 5 of volume calculation Method 1 of the NBBO Program; and (2) decrease the rebates applicable to Tier 1, Tier 5 and Tier 6 for all rebate Levels of the NBBO Program.

First, the Exchange proposes to reduce the minimum volume threshold by 0.05% for Tier 5 of volume calculation Method 1 and make the corresponding change to reduce the maximum volume threshold by 0.05% for Tier 4 of volume calculation Method 1 of the NBBO Program. Accordingly, with the proposed changes to volume calculation Method 1, an Equity Member will qualify for the enhanced rebates in Tier 4 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.08% and less than 0.20% of TCV. Further, an Equity Member will qualify for the enhanced rebates in Tier 5 for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume across all Tapes by achieving an ADAV of at least 0.20% and less than 0.40% of TCV. The Exchange does not propose to change any other volume calculation thresholds for the NBBO Program.

Next, the Exchange proposes to slightly decrease the rebates applicable to Tier 1, Tier 5 and Tier 6 for all rebate Levels of the NBBO Program. With the proposed changes, the Level A rebates will be as follows for Tiers 1, 5 and 6: ($0.00220) per share in Tier 1; ($0.00335) per share in Tier 5; and ($0.00340) per share in Tier 6. The Exchange does not propose to amend the rebate amounts applicable to Level A, Tiers 2, 3 and 4. With the proposed changes, the Level B rebates will be as follows for Tiers 1, 5 and 6: ($0.00225) per share in Tier 1; ($0.00340) per share in Tier 5; and ($0.00345) per share in Tier 6. The Exchange does not propose to amend the rebate amounts applicable to Level B, Tiers 2, 3 and 4. With the proposed changes, the Level C rebates will be as follows for Tiers 1, 5 and 6: ($0.00230) per share in Tier 1; ($0.00345) per share in Tier 5; and ($0.00350) per share in Tier 6. The Exchange does not propose to amend the rebate amounts applicable to Level C, Tiers 2, 3 and 4.

The purpose of these changes is for business and competitive reasons in light of recent volume growth on the Exchange. The Exchange notes that, even with the proposed changes, the base rebates, enhanced rebates and volume requirements of the NBBO Program remain competitive with, or better than, the rebates and volume requirements provided by other exchanges for executions of orders in securities priced at or above $1.00 per share that add displayed liquidity to those exchanges.[20]

Corresponding Changes to the Standard Rates Table and Liquidity Indicator Codes and Associated Fees Table

In connection with the proposed changes to the Level A, Tier 1 (Base) rebate of the NBBO Program described above, the Exchange proposes to amend the Standard Rates table in Section 1)a) of the Fee Schedule for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in all Tapes and the Liquidity Indicator Codes and Associated Fees table in Section 1)b) of the Fee Schedule. In particular, the Exchange proposes to amend the Standard Rates table in Section 1)a) of the Fee Schedule to show the reduced standard rebate from ($0.0024) to now be ($0.0022) per share for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in all Tapes. Further, the Exchange proposes to amend the Liquidity Indicator Codes and Associated Fees table in Section 1)b) of the Fee Schedule to amend Liquidity Indicator Codes ''AA,'' ''AB,'' and ''AC'' to show the reduced standard from ($0.0024) to now be ($0.0022) per share for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in all Tapes. The purpose of these corresponding changes is to ensure the Fee Schedule is accurate and clear in light of the change to the base rebate amount in Level A, Tier 1 of the NBBO Setter Plus Table. The Exchange notes that despite the modest base rebate reduction proposed herein for executions of securities priced at or above $1.00 per share for Added Displayed Volume in all Tapes, the proposed standard rebate—($0.0022) per share—remains higher than, and competitive with, the standard rebates provided by other exchanges for executions of orders in securities priced at or above $1.00 per share that add displayed liquidity.[21]

Proposal To Amend the NBBO Setter Additive Rebate

The Exchange proposes to amend the NBBO Setter Additive Rebate in the

[17] Midpoint ADAV means the ADAV for the current month consisting of Midpoint Peg Orders in securities priced at or above $1.00 per share that execute at the midpoint of the Protected NBBO and add liquidity to the Exchange. A Midpoint Peg Order is a non-displayed Limit Order that is assigned a working price pegged to the midpoint of the PBBO. A Midpoint Peg Order receives a new timestamp each time its working price changes in response to changes in the midpoint of the PBBO. *See* Exchange Rule 2614(a)(3). With respect to the trading of equity securities, the term ''the term ''Protected NBB'' or ''PBB'' shall mean the national best bid that is a Protected Quotation, the term ''Protected NBO'' or ''PBO'' shall mean the national best offer that is a Protected Quotation, and the term ''Protected NBBO'' or ''PBBO'' shall mean the national best bid and offer that is a Protected Quotation. *See* Exchange Rule 1901.

[18] *See* Fee Schedule, Section 1)c), Notes to NBBO Setter Plus Table, note 4.

[19] *See* Fee Schedule, Section 1)c).

[20] *See* Cboe BZX Equities Fee Schedule, Add/Remove Volume Tiers section, *available at https://www.cboe.com/us/equities/membership/fee_schedule/bzx/* (providing an enhanced rebate in Tier 4 of ($0.0028) per share for executions of added displayed volume in securities priced at or above $1.00 per share, so long as the member meets all requirements, including minimum NBBO Time and NBBO Size requirements from a list of specified securities and minimum requirement of ADAV as a percentage of TCV); *see also* NYSE Arca Equities Fee Schedule, *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (providing standard rebates of ($0.0020) per share (Tapes A and C) and ($0.0016) per share (Tape B) for adding displayed liquidity in securities priced at or above $1.00 per share).

[21] *See e.g.,* MEMX LLC (''MEMX'') Equities Fee Schedule, Transaction Fees section, *available at https://info.memxtrading.com/equities-trading-resources/us-equities-fee-schedule/* (providing a standard rebate $0.0015 per share for added displayed volume in securities priced at or above $1.00 per share); *see also* Cboe EDGX Exchange, Inc. (''Cboe EDGX'') Equities Fee Schedule, Standard Rates section, *available at https://www.cboe.com/us/equities/membership/fee_schedule/edgx/* (providing a standard rebate of $0.0016 per share for added displayed volume in securities priced at or above $1.00 per share).

NBBO Setter Plus Table in Section 1)c) of the Fee Schedule. Currently, the Exchange provides an NBBO Setter Additive Rebate of ($0.0003) per share, which applies only to executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume (other than Retail Orders [22]) that set the NBB or NBO on MIAX Pearl Equities with a minimum size of a round lot. The Exchange now proposes to increase the NBBO Setter Additive Rebate from ($0.0003) to ($0.0004) per share for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume (other than Retail Orders) [23] that set the NBB or NBO on MIAX Pearl Equities with a minimum size of a round lot. The purpose of the proposed increase to the NBBO Setter Additive Rebate is to continue to provide an additional incentive for Equity Members to contribute Added Displayed Volume in securities priced at or above $1.00 per share that sets the NBB or NBO on MIAX Pearl Equities, which should benefit all Equity Members by providing greater execution opportunities on the Exchange and contribute to a deeper, more liquid market, to the benefit of all investors and market participants.

Proposal To Establish NBBO First Joiner Additive Rebate

The Exchange proposes to amend the NBBO Setter Plus Table in Section 1)c) of the Fee Schedule to establish the new ''NBBO First Joiner Additive Rebate.'' In particular, the Exchange proposes that the NBBO First Joiner Additive Rebate will be an additive rebate of ($0.0002) per share for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume (other than Retail Orders) [24] for the *first* Equity Member that brings MIAX Pearl Equities to the established NBB or NBO with a minimum size of a round lot. The Exchange notes the NBBO First Joiner Additive Rebate will not apply to executions of orders in securities priced at or above $1.00 per share that join the NBB or NBO on MIAX Pearl Equities with a minimum size of a round lot *after* the first Equity Member's order that brings MIAX Pearl Equities to the established NBB or NBO with a minimum size of a round lot.

The purpose of adopting the NBBO First Joiner Additive Rebate is to further attract aggressively priced displayed liquidity to the Exchange. The Exchange believes that such change will encourage the submission of orders that join the established NBB or NBO on the Exchange that matches the NBB or NBO first established on an away market, in order to receive the additive rebate on such executions and the Exchange believes that the resulting increased submission of such aggressively priced displayed liquidity would enhance market quality by increasing execution opportunities, tightening spreads, encouraging depth, and promoting price discovery on the Exchange. The Exchange notes that NBBO First Joiner Additive Rebate is comparable to other volume-based incentives and discounts, which have been widely adopted by exchanges, and that the Exchange's proposal to provide an additive rebate for an Equity Member's transaction that brings MIAX Pearl Equities to the established NBB or NBO with a minimum size of a round lot is similar in construct to pricing incentives that have been adopted by other exchanges.[25]

Proposal To Establish the Step-Up Rebate

The Exchange proposes to amend the NBBO Setter Plus Table in Section 1)c) of the Fee Schedule to establish a new ''Step-Up Rebate,'' which will be labelled as Note 4 in the Notes section of the NBBO Setter Plus Table.[26] In particular, the Exchange proposes that the Step-Up Rebate will provide an additional rebate of ($0.0001) per share for executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume (other than Retail Orders) [27] for Equity Members that satisfy the following requirements in the relevant month: (1) minimum Displayed ADAV of 0.35% of TCV; and (2) increase in the percentage of Displayed ADAV of at least 0.05% of TCV as compared to the Equity Member's February 2024 [28] Displayed ADAV percentage.[29] The Exchange proposes that the Step-Up Rebate will expire no later than August 31, 2024 (referred to herein as the ''sunset period''),[30] which will be stated in the Fee Schedule. The Exchange will issue an alert to market participants should the Exchange determine that the Step-Up Rebate will expire earlier than August 31, 2024 or if the Exchange determines to amend the criteria or rate applicable to the Step-Up Rebate prior to the end of the sunset period. The Exchange notes other competing equities exchanges offer an enhanced or additive rebate utilizing a volume comparison of the current month to a prior baseline month with a similar ''sunset period.'' [31]

The purpose of this proposed change is to provide an incentive for Equity Members to strive for higher ADAV on the Exchange (above their ADAV in the baseline month of February 2024) to receive the additive Step-Up Rebate for

[22] A ''Retail Order'' is an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. *See* Exchange Rule 2626(a)(2).

[23] The Exchange excludes Retail Orders from participating in the NBBO Setter Additive Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share. *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

[24] The Exchange proposes to exclude Retail Orders from participating in the NBBO First Joiner Additive Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share. *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

[25] *See, e.g.,* Securities Exchange Act Release No. 96471 (December 9, 2022), 87 FR 76648 (December 15, 2022) (SR–MEMX–2022–33) (establishing NBBO Setter/Joiner Tiers with an additive rebate for member's orders that establish the NBBO or establish a new best bid or offer on MEMX that matched the NBBO first established on an away market).

[26] In connection with this change and numbering the proposed Step-Up Rebate as Note 4, the Exchange proposes to renumber Notes 3 and 4 as currently provided for in the Notes section of the NBBO Setter Plus Table, as described further below in this filing.

[27] The Exchange proposes to exclude Retail Orders from participating in the Step-Up Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share. *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

[28] The Exchange will use a baseline ADAV of 0.00% of TCV for firms that become Equity Members of the Exchange after February 2024 for the purpose of the Step-Up Rebate calculation.

[29] The Exchange notes that the proposed Step-Up Rebate will not apply to executions of orders in securities priced below $1.00 per share or executions of orders that constitute added non-displayed liquidity.

[30] The Exchange notes that at the end of the sunset period, the Step-Up Rebate will no longer apply unless the Exchange files a rule filing pursuant to Rule 19b–4 of the Exchange Act with the Commission to amend the criteria terms or update the baseline month to a more recent month.

[31] *See* MEMX Equities Fee Schedule, Liquidity Provision Tiers, Tier 2, *available at https://info.memxtrading.com/equities-trading-resources/us-equities-fee-schedule/* (providing enhanced rebate of ($0.0032) per share if the equity member meets a minimum displayed ADAV requirement in the current month compared to its displayed ADAV of the TCV from September 2023 with a sunset period of March 31, 2024); *see also* Cboe BZX Equities Fee Schedule, Step-Up Tiers section, *available at https://www.cboe.com/us/equities/membership/fee_schedule/bzx/* (providing enhanced rebate of ($0.0032) per share if the equity member meets certain added displayed volume requirements in Tiers 2 or 3 in the current month compared its added displayed volume from May 2019 or January 2022).

qualifying executions of Added Displayed Volume in securities priced at or above $1.00 per share in all Tapes. The Exchange believes that the proposed Step-Up Rebate will encourage the submission of additional Added Displayed Volume to the Exchange, thereby promoting price discovery and contributing to a deeper and more liquid market, which benefits all market participants and enhances the attractiveness of the Exchange as a trading venue. The purpose of including the proposed sunset period in the Fee Schedule is to provide clarity to Equity Members that, unless the Exchange determines to amend or otherwise modify the Step-Up Rebate, the Step-Up Rebate will expire at the end of the sunset period.

Proposed Changes to Notes Section of NBBO Setter Plus Table

The Exchange proposes to make several changes to the notes section of the NBBO Setter Plus Table in Section 1)c) of the Fee Schedule in light of the proposed changes described above. Note 3 currently provides that ''Retail Orders are not eligible for the NBBO Setter Additive Rebate as it applies only to Liquidity Indicator Codes AA, AB and AC.'' The Exchange proposes to move Note 3 to the end of the notes section, renumber it as new ''Note 5,'' and add text that in addition to the NBBO Setter Additive Rebate, Retail Orders will also not be eligible for the proposed NBBO First Joiner Additive Rebate and the Step-Up Rebate. Accordingly, new Note 5 will provide as follows: ''Retail Orders are not eligible for the NBBO Setter Additive Rebate, the NBBO First Joiner Additive Rebate, or the Step-Up Rebate as these rebates only apply to Liquidity Indicator Codes AA, AB and AC.''

Next, in connection with the proposed change to establish the Step-Up Rebate as Note 4 (described above), the Exchange proposes to renumber current Note 4 to now be numbered as Note 3. The Exchange does not propose to amend any of the text of current Note 4 (proposed renumbered Note 3). The purpose of all of these changes is to provide clarity within the Fee Schedule in connection with all of the changes proposed herein.

Implementation

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [32] in general, and furthers the objectives of Section 6(b)(4) of the Act [33] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Equity Members and issuers and other persons using its facilities. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [34] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.

The Exchange operates in a highly fragmented and competitive market in which market participants can readily direct their order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of sixteen registered equities exchanges, and there are a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange had more than approximately 15–16% of the total market share of executed volume of equities trading for the month of February 2024.[35] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange represented approximately 1.73% of the overall market share for the month of February 2024. The Commission and the courts have repeatedly expressed their 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.'' [36]

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 new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance liquidity and market quality in both a broad manner and in a targeted manner with respect to the NBBO Program, in particular, and Added Displayed Volume in securities priced at or above $1.00 per share, in general.

Proposal To Amend Certain Volume Thresholds and Rebates for the NBBO Program

The Exchange believes its proposal to reduce the volume threshold requirement for Tier 5 (and adjacently Tier 4) of volume calculation Method 1 and decrease the rebates applicable to Tier 1, Tier 5 and Tier 6 for all rebate Levels of the NBBO Program provides a reasonable means to continue to encourage Equity Members to not only increase their order flow to the Exchange but also to contribute to price discovery and market quality on the Exchange by submitting aggressively priced displayed liquidity in securities priced at or above $1.00 per share. The Exchange believes that the NBBO Program, as modified with this proposal, continues to be equitable and not unfairly discriminatory because it is open to all Equity Members on an equal basis and provides enhanced rebates that are reasonably related to the value of the Exchange's market quality associated with greater order flow by Equity Members that set the NBB or NBO, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes the proposal is equitable and not unfairly discriminatory because it is designed to incentivize the entry of aggressively priced displayed liquidity that will create tighter spreads, thereby promoting price discovery and market quality on the Exchange to the benefit of all Equity Members and public investors.

In addition, the Exchange believes its proposal to reduce the volume threshold requirement for Tier 5 (and adjacently Tier 4) of volume calculation Method 1 and decrease the rebates applicable to Tier 1, Tier 5 and Tier 6 for all rebate Levels of the NBBO Program is reasonable because, even with the proposed changes, the base rebates,

[32] 15 U.S.C. 78f(b).

[33] 15 U.S.C. 78f(b)(4).

[34] 15 U.S.C. 78f(b)(5).

[35] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/* (last visited March 26, 2024).

[36] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37499 (June 29, 2005).

enhanced rebates and volume requirements of the NBBO Program remain competitive with, or better than, the rebates and volume requirements provided by other exchanges for executions of orders in securities priced at or above $1.00 per share that add displayed liquidity to those exchanges.[37]

Corresponding Changes to the Standard Rates Table and Liquidity Indicator Codes and Associated Fees Table

The Exchange believes its proposal to amend the Standard Rates table and Liquidity Indicator Codes and Associated Fees table to show the reduced standard rebate of ($0.0022) per share for Added Displayed Volume in securities priced at or above $1.00 per share in all Tapes is reasonable because these corresponding changes are to ensure the Fee Schedule is accurate and clear in light of the change to the base rebate amount in Level A, Tier 1 of the NBBO Setter Plus Table. The Exchange believes that even with the proposed reduced standard rebate for Added Displayed Volume in securities priced at or above $1.00 per share in all Tapes, the proposal is reasonable, equitably allocated and not unfairly discriminatory because the proposed standard rebate—($0.0022) per share—remains higher than, and competitive with, the standard rebates provided by other exchanges for executions of orders in securities priced at or above $1.00 per share that add displayed liquidity.[38]

Proposal To Amend the NBBO Setter Additive Rebate

The Exchange believes its proposal to increase the NBBO Setter Additive Rebate to ($0.0004) per share for Added Displayed Volume (other than Retail Orders) for executions of orders in securities priced at or above $1.00 per share that set the NBB or NBO on MIAX Pearl Equities with a minimum size of a round lot is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes it will continue to provide an additional incentive for Equity Members to contribute Added Displayed Volume in securities priced at or above $1.00 per share that sets the NBB or NBO on MIAX Pearl Equities. In turn, this should benefit all Equity Members by providing greater execution opportunities on the Exchange and contribute to a deeper, more liquid market, to the benefit of all investors and market participants. Further, the NBBO Setter Additive Rebate is available to all Equity Members of the Exchange that transact in securities priced at or above $1.00 per share in all Tapes. The Exchange believes it is reasonable and not unfairly discriminatory to continue to exclude Retail Orders from participating in the NBBO Setter Additive Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share.[39]

Proposal To Establish the NBBO First Joiner Additive Rebate

The Exchange believes its proposal to establish the NBBO First Joiner Additive Rebate is reasonable because it should attract aggressively priced displayed liquidity to the Exchange, which will encourage the submission of orders that join the established NBB or NBO on the Exchange. This should result in increased orders of aggressively priced displayed liquidity, which would enhance the Exchange's market quality by increasing execution opportunities, tightening spreads, and promoting price discovery on the Exchange to the benefit of all market participants. The Exchange believes its proposal to establish the NBBO First Joiner Additive Rebate is equitably allocated and not unfairly discriminatory because it will be available to all Equity Members and is comparable to other volume-based incentives and discounts, which have been widely adopted by exchanges.[40] The Exchange believes it is reasonable and not unfairly discriminatory to exclude Retail Orders from participating in the NBBO First Joiner Additive Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share.[41]

Proposal To Establish the Step-Up Rebate

The Exchange believes that the proposed Step-Up Rebate is comparable to other incentives currently offered by other exchanges,[42] and is reasonable, equitable and not unfairly discriminatory for these same reasons, as it provides Equity Members with an additional incentive to achieve a certain volume threshold on the Exchange. Further, the proposed Step-Up Rebate will be available to all Equity Members and is designed to encourage Equity Members to increase their orders of Added Displayed Volume in order to qualify for the additive rebate for qualifying executions, which, in turn, the Exchange believes would encourage the submission of additional Added Displayed Volume to the Exchange, thereby promoting price discovery and contributing to a deeper and more liquid market to the benefit of all market participants. The Exchange believes it is reasonable and not unfairly discriminatory to continue to exclude Retail Orders from participating in the Step-Up Rebate because executions of orders in securities priced at or above $1.00 per share for Added Displayed Volume in Retail Orders already receive an enhanced rebate of ($0.0037) per share.[43]

Proposed Changes to Notes Section of NBBO Setter Plus Table

The Exchange believes its proposal to renumber and amend the Notes section of the NBBO Setter Plus Table is reasonable because it will provide additional clarity within the Fee Schedule. In particular, the Exchange believes it is reasonable to set forth in new Note 5 that Retail Orders will note be eligible for the NBBO Setter Additive Rebate, the NBBO First Joiner Additive Rebate, or the Step-Up Rebate as these rebates only apply to Liquidity Indicator Codes AA, AB and AC, which will provide clarity to Equity Members about the applicability of such rebates.

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.

Intra-Market Competition

The Exchange does not believe that the proposal will impose any burden on intra-market competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes its proposed changes to the NBBO Program, increase to the NBBO Setter Additive Rebate, adoption of the NBBO First Joiner Additive Rebate, and adoption of the Step-Up Rebate would incentivize Equity Members to submit additional orders that add liquidity to the Exchange, thereby contributing to a deeper and more liquid market and promoting price discovery and market quality on the Exchange to the benefit of all market participants and enhancing

[37] *See supra* note 20.

[38] *See supra* note 21.

[39] *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

[40] *See supra* note 25.

[41] *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

[42] *See supra* note 31.

[43] *See* Fee Schedule, Section 1)b), Liquidity Indicator Code ''AR''.

the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Equity Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. As described above, the opportunity to qualify for the proposed new NBBO First Joiner Additive Rebate, Step-Up Rebate, or increased NBBO Setter Additive Rebate, and thus receive the proposed rebates or additive rebates for qualifying executions of Added Displayed Volume, would be available to all Equity Members that meet the associated requirements, and the Exchange believes the proposed changes provide such incentives is reasonably related to the enhanced market quality that they are designed to promote. As such the Exchange does not believe the proposed changes would impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purpose of the Act.

Intermarket Competition

The Exchange believes the proposed changes will benefit competition, and the Exchange notes that it operates in a highly competitive market. Equity Members have numerous alternative venues they may participate on and direct their order flow to, including fifteen other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently had more than 15–16% of the total market share of executed volume of equities trading for the month of February 2024.[44] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow in response to new or different pricing structures being introduced to the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates generally, including with respect to executions of Added Displayed Volume, and market participants can readily choose to send their orders to other exchanges and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes are competitive proposals through which the Exchange seeks to encourage certain order flow to the Exchange and to promote market quality through pricing incentives that are similar in structure and purpose to pricing programs at other Exchanges, including the incentives with a sunset period such as the Step-Up Rebate.[45] Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar incentives to market participants that enhance market quality.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and self-regulatory organization (''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.'' [46] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. circuit stated: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possess a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . .''.[47] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[44] *See supra* note 31 [*sic*].

[45] *See supra* notes 20, 25, and 31.

[46] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[47] *See NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

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

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[48] and Rule 19b–4(f)(2) [49] 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–18 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–2024–18. 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 (*https://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

[48] 15 U.S.C. 78s(b)(3)(A)(ii).

[49] 17 CFR 240.19b–4(f)(2).

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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–18 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08574 Filed 4–22–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99974; File No. SR–NYSE–2024–22]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 123D

April 17, 2024.

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 April 11, 2024, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 123D (Halts in Trading) to set forth specific requirements for halting and resuming trading in a security that is subject to a reverse stock split. 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

In conjunction with the increase in overall reverse stock splits in recent years, the Exchange proposes to amend Rule 123D (Halts in Trading) to set forth specific requirements for halting and resuming trading in a security that is subject to a reverse stock split.

Background

The Commission recently approved a proposal filed by The Nasdaq Stock Exchange (''Nasdaq'') providing for a regulatory halt at the end of trading on the day immediately before the market effective date of a reverse stock split and a delayed opening of the security on the market effective date of the reverse stock split.[4] In its filing, Nasdaq noted that it had observed a recent increase in reverse stock split activity in the current market environment.

The Exchange has not itself experienced the increase in the number of reverse stock splits that Nasdaq described in its filings. Nevertheless, the Exchange proposes to adopt similar changes at the request of market participants who say that they would benefit from a consistent approach across exchanges with respect to regulatory halt rules around reverse stock splits. The Exchange believes that harmonizing its rules with Nasdaq's in this area would enhance investor protection and maintain fair and orderly markets by minimizing the chance that market participants might make erroneous trades in a security because they were unaware that it had undergone a reverse stock split.

Accordingly, the Exchange proposes to adopt amendments to its trading halt rules to require the Exchange to declare a regulatory halt in trading before the end of after-hours trading on the day immediately before the market effective date of a reverse stock split, and to open the security on the market effective date of a reverse stock split with a Trading Halt Auction[5] starting at 9:30 a.m., at the start of the Exchange's Core Trading Session.[6] This proposed change is modeled on the recently-approved Nasdaq rule.

This change would help reduce the potential for market participants' misunderstanding of the impact on the value of the issuer' securities resulting from investors' lack of advance knowledge of the reverse stock split, as well as errors resulting in a material effect on the market resulting from market participants' processing of the reverse stock split, including incorrect adjustment or entry of orders.

Proposed Amendment to Rule 123D

The Exchange currently processes reverse stock splits overnight, with the security available for trading on other markets at 4:00 a.m.[7] on a split-adjusted basis. Market participants have recently expressed concerns with allowing trading on an adjusted basis during those early trading sessions, noting that it is not optimal because system errors or problems with orders may go unnoticed for a period of time when a security that has undergone a reverse stock split opens for trading with the other thousands of securities. These errors have the potential to adversely affect investors, market participants, and the issuer. For example, problems

[50] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 98878 (November 7, 2023) (SR–NASDAQ–2023–036) (approving halt provisions with respect to reverse stock splits).

[5] The term ''Trading Halt Auction'' is defined in Rule 7.35(a)(1)(B) as an auction ''that reopens trading following a trading halt or pause.'' The Trading Halt Auction would be effectuated by the security's designated market maker (''DMM'') pursuant to Rule 7.35A (DMM-Facilitated Core Open and Trading Halt Auctions). An Exchange-listed security that opens trading for the day with a Trading Halt Auction would not undergo a Core Open Auction (defined in Rule 7.35(a)(1)(A)).

[6] The term ''Core Trading Session'' is defined in Rule 7.34(a)(2).

[7] All times referred to in this filing are Eastern Time.

in connection with the processing of a reverse stock split could result in a broker executing trades selling more shares than customers held in their accounts, resulting in a temporary short position.

As such, the Exchange believes it is appropriate to impose a regulatory halt, which would prohibit pre-market trading immediately after a reverse stock split, and to re-open trading in such securities using a Trading Halt Auction. These changes would allow the Exchange and market participants to better detect any errors or problems with orders for the security resulting from the reverse stock split before trading in the security begins and thereby avoid any material effect on the market.

The Exchange proposes to add new subparagraph (f) to Rule 123D, which would provide that the Exchange will halt trading in a security for which the Exchange is the Primary Listing Market [8] before the end of post-market trading on other markets on the day immediately before the market effective date of a reverse stock split. Such a trading halt due to a reverse stock split would be mandatory pursuant to proposed Rule 123D(f). In general, the Exchange expects to initiate the halt at 7:50 p.m., prior to the end of post-market trading on other markets at 8:00 p.m. on the day immediately before the split is effective.[9]

Proposed Rule 123D(f) would further provide that trading in the security will resume with a Trading Halt Auction starting at 9:30 a.m.[10] on the day the reverse stock split is effective.[11] The Exchange believes that this halt and delayed opening [12] would give sufficient time for investors to review their orders and the quotes for the security and allow market participants to ensure that their systems have properly adjusted for the reverse stock split.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposal removes impediments to and perfects the mechanism of a free and open market and a national market system and protects investors and the public interest. The Exchange is proposing these changes at the request of market participants who say that they would benefit from a consistent approach across exchanges with respect to regulatory halt rules around reverse stock splits. As such, the Exchange believes that harmonizing its rules with Nasdaq's in this area would enhance investor protection and maintain fair and orderly markets by minimizing the chance that market participants might make erroneous trades in a security because they were unaware that it had undergone a reverse stock split.

The Exchange believes that its proposed rule change establishing a reverse stock split trading halt rule would protect investors by giving the Exchange non-discretionary authority to act in situations where it is necessary to maintain fair and orderly markets, such as when a security is subject to a reverse stock split and companies have not updated their systems to account for the new stock price. It would also ensure that the process for resuming trading following a reverse stock split halt is consistent with other types of halts initiated by the Exchange. Currently, none of the Exchange's rules provide authority to pre-emptively halt the trading in a security undergoing a significant corporate action that could lead to investor or market confusion.

The Exchange believes that the proposed amendments would provide greater transparency and clarity with respect to the manner in which trading would be halted due to a reverse stock split, and the process through which that halt would be implemented and terminated. Particularly, the Exchange would not have discretion in determining whether to declare a trading halt in a security following the declaration of a reverse stock split. Rather, following the reverse stock split of a security for which the Exchange is the Primary Listing Market, trading in the security would halt prior to the close of the post-market trading session on other markets on the day immediately before the market effective date of the reverse stock split. The Exchange also believes it is appropriate

[8] The term ''Primary Listing Market'' is defined in Section XI(a)(i)(H) of the CTA Plan as ''the national securities exchange on which an Eligible Security is listed. If an Eligible Security is listed on more than one national securities exchanges, Primary Listing Market means the exchange on which the security has been listed the longest.''

[9] It is the Exchange's policy not to halt a security after 4:00 p.m. in advance of a material news disclosure by a listed company, but the Exchange does implement regulatory halts after 4:00 p.m. when necessary for other reasons. In the case of a security undergoing a reverse stock split, initiating the halt at approximately 7:50 p.m. would provide the Exchange with a limited buffer to ensure that trading in a security that is undergoing a reverse stock split would not continue after the end of post-market trading. While the Exchange does not anticipate halting a security that undergoes a reverse stock split sooner than 7:50 p.m., the Exchange may halt trading earlier than 7:50 p.m. for other reasons as described elsewhere in Rule 123D or Rule 7.18. The Exchange would provide notice of the halt through the SIP and on the Exchange's trading halt web page at *https://www.nyse.com/trade-halt.*

[10] The Exchange's affiliates NYSE American LLC (''NYSE American'') and NYSE Arca, Inc. (''NYSE Arca'') have each filed similar rule changes proposing to re-open a security subject to a reverse stock split trading halt with a Trading Halt Auction that would take place at 9:00 a.m., thirty minutes before the Core Trading Session would start. *See* SR–NYSEAMER–2024–24 and SR–NYSEARCA–2024–29. Both NYSE American and NYSE Arca have Early Trading Sessions, and thus the 9:00 a.m. Trading Halt Auction would take place while trading on those exchanges is already in progress. *See* NYSE American Rule 7.34E(a)(1) and NYSE Arca Rule 7.34–E(a)(1) (defining ''Early Trading Session''). Because the Exchange does not have an early trading session for securities for which it is the Primary Listing Market, the Exchange instead proposes that a security subject to a reverse stock split trading halt would re-open with a Trading Halt Auction starting at 9:30 a.m., at the start of the Exchange's Core Trading Session. The Exchange believes that re-opening the security with a Trading Halt Auction starting at 9:30 a.m. would promote fair and orderly trading because it would provide market participants and the Exchange ample opportunity to notice errors or problems with orders for the security due to the reverse stock split. In addition, the Exchange believes that re-opening the security with a Trading Halt Auction starting at 9:30 a.m. (instead of at 9:00 a.m. as on NYSE American and NYSE Arca) would promote fair and orderly trading because it would follow the Exchange's usual opening process for securities that are re-opening at the start of the Core Trading Session after a regulatory halt. The Exchange believes that this approach is preferable to creating an entirely new trading session commencing at 9:00 a.m. solely for the re-opening of securities listed on the Exchange subject to a regulatory halt in advance of a reverse stock split, which the Exchange believes would cause confusion among market participants.

[11] The Exchange may change the resumption time if, for example, there was ''Extraordinary Market Activity,'' as defined in the CTA Plan, that could interfere with a fair and orderly resumption at the start of Core Trading Hours. The Exchange will provide notice of the re-opening of the security through the SIP and on the Exchange's trading halt web page at *https://www.nyse.com/trade-halt.*

[12] Trading in a security that has undergone a reverse stock split would have a delayed opening because following the reverse stock split, the security would not be available for early-session trading at 4:00 a.m. on away markets, but would instead re-open with a Trading Halt Auction at the start of the Core Trading Session. Orders that have been entered for execution prior to the Trading Halt Auction and not canceled would be eligible to execute in the Trading Halt Auction.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

to re-open the security with a Trading Halt Auction on the effective date of the reverse stock split because doing so would give the Exchange and market participants an opportunity to identify any orders in a security that has undergone a reverse stock split that have not correctly adjusted to the security's new stock price. The proposed changes seek to achieve consistency with respect to the initiation and termination of a trading halt with respect to securities that have undergone a reverse stock split, while maintaining a fair and orderly market, protecting investors, and protecting the public interest.

Additionally, the Exchange believes that establishing a mandatory trading halt for securities that have undergone a reverse stock split and resuming trading thereafter promotes fair and orderly markets and the protection of investors because it allows the Exchange to protect the broader interests of the national market system and addresses potential concerns that system errors may affect immediate trading in those securities. The Exchange believes that given the increase in companies effecting reverse stock splits, the proposal would help the Exchange reduce the potential for errors resulting in a material effect on the market resulting from market participants' processing of the reverse stock split, including incorrect adjustment or entry of orders.

The Exchange further believes that re-opening a security subject to a reverse stock split with a Trading Halt Auction starting at 9:30 a.m. would promote fair and orderly trading because it would provide market participants and the Exchange ample opportunity to notice errors or problems with orders for the security due to the reverse stock split. In addition, the Exchange believes that re-opening the security with a Trading Halt Auction starting at 9:30 a.m. (instead of at 9:00 a.m. as on NYSE American and NYSE Arca) [15] would promote fair and orderly trading because it would follow the Exchange's usual opening process for securities that are re-opening at the start of the Core Trading Session after a regulatory halt. The Exchange believes that this approach is preferable to creating an entirely new trading session commencing at 9:00 a.m. solely for the re-opening of securities listed on the Exchange subject to a regulatory halt in advance of a reverse stock split, which the Exchange believes would cause confusion among market participants.

Based on the foregoing, the Exchange believes that the proposal is consistent with the Act because it would promote just and equitable principles of trade and would remove any impediments to a free and open market and a national market system by allowing sufficient time for investors to review their orders and the quotes for a security that has undergone a reverse stock split, and allow market participants to ensure that their systems have properly accounted for the reverse stock split. As discussed previously, the Exchange believes that the proposed amendments establishing the authority and process for reverse stock split trading halts and the resumption of trading is consistent with the Act, which itself imposes obligations on exchanges with respect to issuers that are listed.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of Section 6(b)(8) of the Act.[16]

The Exchange believes that the proposal will not impose a burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change is designed to protect investors and facilitate a fair and orderly market, which are both important purposes of the Act. To the extent that there is any impact on intermarket competition, it is incidental to these objectives. In addition, at least one other exchange (Nasdaq) has already adopted a substantially similar rule. The Exchange believes that harmonizing its rules with Nasdaq's in this area would minimize the chance that market participants might make erroneous trades in a security because they were unaware that it had undergone a reverse stock split.

The Exchange does not believe that the proposed rule change imposes a burden on intra-market competition because the provisions apply to all market participants and issuers on the Exchange equally. In addition, information regarding the timing of reverse stock splits and the halting and resumption of trading in connection with the effecting of reverse splits would be disseminated using several freely-accessible sources to ensure the broad availability of this information.

In addition, the proposal includes provisions related to the declaration and timing of trading halts and the resumption of trading that are designed to prevent any advantage to those who can react more quickly than other market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [17] and Rule 19b–4(f)(6) thereunder.[18] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[19]

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) [20] 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:

[15] *See supra* note 10.

[16] 15 U.S.C. 78f(b)(8).

[17] 15 U.S.C. 78s(b)(3)(A)(iii).

[18] 17 CFR 240.19b–4(f)(6).

[19] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[20] 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSE–2024–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2024–22 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08569 Filed 4–22–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99983; File No. SR–CboeEDGA–2024–014]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Regarding Dedicated Cores

April 17, 2024.

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 April 12, 2024, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule to amend the fees and increase the maximum cap for Dedicated Cores.[3]

By way of background, the Exchange recently began to allow Users [4] to assign a Single Binary Order Entry (''BOE'') logical order entry port [5] to a single dedicated Central Processing Unit (CPU Core) (''Dedicated Core''). Historically, CPU Cores had been shared by logical order entry ports (*i.e.,* multiple logical ports from multiple firms may connect to a single CPU Core). Use of Dedicated Cores however, can provide reduced latency, enhanced throughput, and improved performance since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core instead of sharing that power with other firms. This offering is completely voluntary and is available to all Users that wish to purchase Dedicated Cores. Users may utilize BOE logical order entry ports on shared CPU Cores, either in lieu of, or in addition to, their use of Dedicated Core(s). As such, Users are able to operate across a mix of shared and dedicated CPU Cores which the Exchange believes provides additional risk and capacity management. Further, Dedicated Cores are not required nor necessary to participate on the Exchange and as such Users may opt not to use Dedicated Cores at all.

The Exchange currently assesses the following monthly fees for those Users that wish to use Dedicated Cores: $650 per Dedicated Core for the first 3 Dedicated Cores; $1,050 per Dedicated Core for the 4th–6th Dedicated Cores; and $1,450 per Dedicated Core for 7 or more Dedicated Cores. The proposed fees are progressive and are assessed and applied in their entirety and are not

[3] The Exchange initially filed the proposed rule change on April 1, 2024 (SR–CboeEDGA–2024–012). On April 12, 2024, the Exchange withdrew that filing and submitted this filing.

[4] A User may be either a Member or Sponsored Participant. The term ''Member'' shall mean any registered broker or dealer that has been admitted to membership in the Exchange, limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange. A Sponsored Participant may be a Member or non-Member of the Exchange whose direct electronic access to the Exchange is authorized by a Sponsoring Member subject to certain conditions. See Exchange Rule 11.3.

[5] Users may currently connect to the Exchange using a logical port available through an application programming interface (''API''), such as the Binary Order Entry (''BOE'') protocol. A BOE logical order entry port is used for order entry.

prorated. The monthly Dedicated Core fees are in addition to the standard per port fee assessed to Users for the BOE Logical Port(s) ports assigned to the Dedicated Core(s).[6] The Exchange notes the current standard fees assessed for BOE Logical Ports, whether used with Dedicated or shared CPU cores, are applicable and unchanged.[7]

Since the Exchange currently has finite amount of space in its data centers in which its servers (and therefore corresponding CPU Cores) are located, the Exchange has also prescribed a maximum limit on the number of Dedicated Cores that Users may purchase each month. Particularly, the Exchange currently provides that Members are limited to a maximum number of 10 Dedicated Cores and Sponsoring Members are limited to a maximum number of 4 Dedicated Cores for each of their Sponsored Access relationships.[8] The purpose of establishing these limits is to manage the allotment of Dedicated Cores in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an unlimited number of Dedicated Cores.

The Exchange now proposes to amend these fees and maximum limits. First the Exchange proposes to provide up to two Dedicated Cores to all Users who wish to use Dedicated Cores, at no additional cost. The Exchange also proposes to amend the Fees such that it proposes to charge: $650 per Dedicated Core for 3–10 Dedicated Cores; $850 per Dedicated Core for 11–15 Dedicated Cores; and $1,050 per Dedicated Core for 16 or more Dedicated Cores. The Exchange notes the proposed fees will continue to be progressive and the Exchange proposes to update the current example in the fees schedule to maintain clarity as to how they are applied.[9]

The Exchange also proposes to increase the current maximum number of Dedicated Cores that Users may purchase. In particular, the Exchange continually monitors market participant demand and resource availability and endeavors to adjust the limit if and when the Exchange is able to accommodate additional CPU Cores (including Dedicated Cores). In response to market participant demand and the ability to now accommodate additional Dedicated Cores, the Exchange is proposing to double the current maximum of Dedicated Cores that Users may purchase. Particularly, the Exchange proposes to provide that Members will be limited to a maximum number of 20 Dedicated Cores [10] and Sponsoring Members will be limited to a maximum number of 8 Dedicated Cores for each of their Sponsored Access relationships.[11] The Exchange notes that it will continue monitoring Dedicated Core interest by all Users and allotment availability with the goal of increasing these limits to meet Users' needs.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [14] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) [15] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed changes are reasonable because they provide any Users who wishes to utilize Dedicated Cores up to two Dedicated Cores at no additional cost. Additionally, the proposed changes generally result in reduced fees for Users. For example, only the first three Dedicated Cores are currently assessed the lower $650 per Dedicated Core rate and Dedicated Core quantities above 3 are assessed a higher rate of either $1,050 or $1,450, depending on how many Dedicated Cores a User purchased. As proposed, Users not only get the first two Dedicated Cores for free, but up to 8 additional Dedicated Cores at the lower $650 rate. The Exchange also proposes to reduce the fee rates for the next two tiers as well (*i.e.,* $850 per Dedicated Cores for 11–15 Dedicated Cores and $1,050 for 16–20 Dedicated Cores).

The Exchange also believes the proposed fees are reasonable as Dedicated Cores provide a valuable service that can provide reduced latency, enhanced throughput, and improved performance compared to use of a shared CPU Core since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core. Dedicated Cores continue to not be necessary for trading and as noted above, are entirely optional. Indeed, Users can continue to access the Exchange through shared CPU Cores at no additional cost. Depending on a firm's specific business needs, the proposal enables Users to choose to use Dedicated Cores in lieu of, or in addition to, shared CPU Cores (or as noted, not use Dedicated Cores at all). The Exchange believes the proposal to operate across a mix of shared and dedicated CPU Cores may further provide additional risk and capacity management. If a User finds little benefit in having Dedicated Cores however, or determines Dedicated Cores

[6] The Exchange currently assesses $550 per port per month. *See* Cboe EDGA Equities Fee Schedule.

[7] *See* Cboe U.S. Equities Fees Schedules, EDGA Equities, Logical Port Fees.

[8] The Exchange announced the initial limit via Exchange Notice which was issued on January 29, 2024. *https://cdn.cboe.com/resources/release_notes/2024/Cboe-Global-Markets-to-Introduce-Cboe-Dedicated-Cores-for-EDGA-Equities.pdf.*

[9] Particularly, the Exchange will provide that if a User were to purchase 11 Dedicated Cores, it will be charged a total of $6,050 per month ($0 * 2 + $650 * 8 + $850 * 1).

[10] The prescribed maximum quantity of Dedicated Cores for Members applies regardless of whether that Member purchases the Dedicated Cores directly from the Exchange and/or through a Service Bureau. In a Service Bureau relationship, a customer allows its MPID to be used on the ports of a technology provider, or Service Bureau. One MPID may be allowed on several different Service Bureaus.

[11] The fee tier(s) applicable to Sponsoring Members are determined on a per Sponsored Access relationship basis and not on the combined total of Dedicated Cores across Sponsored Users. For example, under the proposed changes, a Sponsoring Member that has two Sponsored Access relationships is entitled to a total of 16 Dedicated Cores for those 2 Sponsored Access relationships but would be assessed fees separately based on the 8 Dedicated Cores for each Sponsored User (instead of combined total of 16 Dedicated Core). For example, a Sponsoring Member with 2 Sponsored Access relationships would be provided 2 Dedicated Cores at no additional cost for each Sponsored User under Tier 1 (total of 4 Dedicated Cores at no additional cost) and provided an additional 6 Dedicated Cores for each Sponsored User under Tier 2 (total 12 Dedicated Cores) at $650 per month.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

[15] 15 U.S.C. 78f(b)(4).

are not cost-efficient for its needs or does not provide sufficient value to the firm, such User may continue its use of the shared CPU Cores, unchanged or determine not to purchase additional Dedicated Cores. Indeed, the Exchange has no plans to eliminate shared CPU Cores nor to require Users to purchase Dedicated Cores.

The Exchange also believes that the proposed Dedicated Core fees are equitable and not unfairly discriminatory because they continue to be assessed uniformly to similarly situated users in that all Users who choose to purchase Dedicated Cores will be subject to the same proposed tiered fee schedule. Further all Users are entitled to up to 2 Dedicated Cores at no additional cost. The Exchange believes the proposed ascending fee structure is also reasonable, equitable and not unfairly discriminatory as it is designed so that firms that use a higher allotment of the Exchange's finite number of Dedicated Cores pay higher rates, rather than placing that burden on market participants that have more modest needs who will have the flexibility of obtaining Dedicated Cores at lower price points in the lower tiers. As such, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the ascending fee structure reflects the resources consumed by the various needs of market participants—that is, the lowest Dedicated Core consuming Users pay the least, and highest Dedicated Core consuming Users pay the most. Other exchanges similarly assess higher fees to those that consume more Exchange resources.[16] It's also designed to encourage firms to manage their needs in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an additional number of Dedicated Cores.

The Exchange also believes it's reasonable, equitable and not unfairly discriminatory to increase the maximum number of Dedicated Cores permitted because Users will be able to avail themselves of additional Dedicated Cores should they so choose. As noted above, the Exchange continually monitors market participant demand and resource availability with the goal to increase the Dedicated Cores limits to meet Users' needs if and when the Exchange is able to do so. The Exchange proposes to increase the limits for Dedicated Cores based on recent market participant demand and the ability to accommodate additional Dedicated Cores as compared to when the Exchange first launched Dedicated Cores. The Exchange notes that it's reasonable to still maintain a maximum number of Dedicated Cores Users can purchase because the Exchange continues to have a finite amount of space in its data centers. The proposed limits also apply uniformly to similarly situated market participants (*i.e.* all Members are subject to the same Exchange-prescribed limit and all Sponsored Participants are subject to the same Exchange-prescribed limit, respectively). The Exchange believes it's not unfairly discriminatory to provide for different limits for different types of users. For example, the Exchange believes it's not unfairly discriminatory to provide for an initial lower limit to be allocated for Sponsored Participants because unlike Members, Sponsored Participants are able to access the Exchange without paying a Membership Fee. Members also have more regulatory obligations and risk that Sponsored Participants do not. For example, while Sponsored Participants must agree to comply with the Rules of the Exchange, it is the Sponsoring Member of that Sponsored Participant that remains ultimately responsible for all orders entered on or through the Exchange by that Sponsored Participant. The industry also has a history of applying fees differently to Members as compared to Sponsored Participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary in furtherance of the purposes of the Act because the proposed tiered fee structure will apply equally to all similarly situated Users that choose to use Dedicated Cores. As discussed above, Dedicated Cores are optional and Users may choose to utilize Dedicated Cores, or not, based on their views of the additional benefits and added value provided by utilizing a Dedicated Core. The Exchange believes the proposed fee will be assessed proportionately to the potential value or benefit received by Users with a greater number of Dedicated Cores and notes that Users may determine at any time to cease using Dedicated Cores. As discussed, Users can also continue to access the Exchange through shared CPU Cores at no additional cost. Finally, all Users will be entitled to two Dedicated Cores at no additional cost.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market, including competition for exchange memberships. Market Participants have numerous alternative venues that they may participate on, including 15 other equities exchanges, as well as off-exchange venues, where competitive products are available for trading. Indeed, participants can readily choose to submit their order flow to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [17] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[18] Accordingly, the Exchange does not believe its proposed change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[16] See also Cboe U.S. Options Fees Schedule, BZX Options, Options Logical Port Fees, Ports with Bulk Quoting Capabilities.

[17] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[18] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and paragraph (f) of Rule 19b–4 [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 will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGA–2024–014 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–CboeEDGA–2024–014. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGA–2024–014 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08575 Filed 4–22–24; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99978; File No. SR–CBOE–2024–020]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Options Series Program in Rule 4.5(d)

April 17, 2024.

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 April 15, 2024, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') 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 Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the Short Term Options Series Program in Rule 4.5(d). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Rule 4.5(d) (Series of Options Contracts Open for Trading). Specifically, the Exchange proposes to expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (''IWM''), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM.

Currently, Table 1 in Rule 4.5(d) specifies each symbol that qualifies as a Short Term Option Daily Expiration.[5] Today, Table 1 permits the listing and trading of Monday Short Term Option

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). See Rule 4.5(d).

Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[6] The listing and trading of Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 4.5(d).

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (''SPY'') and the INVESCO QQQ TrustSM, Series 1 (''QQQ'') may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[7] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Wednesday Short Term Option Expiration Date'').[8]

In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[9]

The interval between strike prices for the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday IWM Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[10] Rule 4.5, Interpretation and Policy .07(b) provides that, notwithstanding any Rule 4.5, Interpretation and Policy .01 and Interpretation and Policy .07(a), the interval of strike prices on options on IWM will be $1 or greater.[11] Further, Rule 4.5, Interpretation and Policy .15 [sic] provides that, notwithstanding Rule 4.5, Interpretation and Policy .01, the Exchange may open for trading series at $0.50 or greater strike price intervals where the strike price is less than $75 and $1.00 [sic]. Specifically, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to Rule 4.5(d), with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[12] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[13] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well. With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to monthly option series, Short Term Option Daily Expirations expire in the same week in which monthly option series on the same class expire.[14] Further, as is the case today with other Tuesday and Thursday Short Term Option Daily Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[15] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below table sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2023 in the options industry.[16] The Exchange notes that during this time period all options exchanges mitigated weekly strike intervals.

[6] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 in Rule 4.5(d) from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed pursuant to the Short Term Option Series.

[7] *See* Rule 4.5(d).

[8] *Id.*

[9] Today, IWM may trade on Mondays and Wednesdays, in addition to Fridays, as is the case for all options series.

[10] *See* Rule 4.5(d)(5).

[11] Options on Units of the Standard & Poor's Depository Receipts Trust (''SPY''), iShares Core S&P 500 ETF (''IVV''), PowerShares QQQ Trust (''QQQ''), and the SPDR Dow Jones Industrial Average ETF (''DIA'') are also subject to Rule 4.5, Interpretation and Policy .07(b) strike intervals.

[12] *See* Rule 4.5(d)(1).

[13] *See* Rule 4.5(d)(1).

[14] *See* Rule 4.5(d)(2).

[15] *See* Rule 4.5(d).

[16] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	62.82
Weekly	17.22
LEAP	17.77
Quarterly	2.20

Similar to SPY and QQQ, the Exchange would limit the number of Short Term Option Daily Expirations for IWM to two expirations for Tuesday and Thursday expirations while expanding the Short Term Option Series Program to permit Tuesday, and Thursday expirations for IWM. Expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in IWM will account for the addition of 6.77% of strikes for IWM.[17] With respect to the impact to the Short Term Option Series Program on IWM overall, the impact would be a 20% increase in strikes.[18] With respect to the impact to the Short Term Options Series Program overall, the impact would be a 0.1% increase in strikes.[19] Trading Permit Holders will continue to be able to expand hedging tools because all days of the week would be available to permit Trading Permit Holders to tailor their investment and hedging needs more effectively in IWM.

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	35.13
Weekly	48.30
LEAP	12.87
Quarterly	3.70

Weeklies comprise 48.30% of the total volume of options contracts.[20] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants. The introduction of IWM Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[21] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[22] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[23] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure. In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. The Exchange currently lists SPY and QQQ Tuesday and Thursday Short Term Daily Expirations.[24]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similar to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[25] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on a business day in which monthly options series or Quarterly Options Series expire.[26] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday IWM Short Term Daily Expirations.

[17] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[18] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[19] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[20] This table sets forth industry volume. Weeklies comprise 48.30% of volume while only comprising 17.22% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] *Id.*

[24] *See* Rule 4.5(d).

[25] *See* Rule 4.5(d)(2).

[26] *See* Rule 4.5(d).

Finally, the Exchange notes the proposed rule change is substantively the same as a rule change proposed by ISE, which the Commission recently approved.[27]

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. Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on the Exchange.[28] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[29] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[27] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

[28] *See* Rule 4.5(d).

[29] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[30] and Rule 19b–4(f)(6) thereunder.[31] 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[32] and subparagraph (f)(6) of Rule 19b–4 thereunder.[33]

A proposed rule change filed under Rule 19b–4(f)(6)[34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[35] the Commission may 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 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[36] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as its competitor exchanges, thus creating competition among Short Term Option Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[37]

[30] 15 U.S.C. 78s(b)(3)(A)(iii).

[31] 17 CFR 240.19b–4(f)(6).

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] See supra note 27.

[37] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CBOE–2024–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CBOE–2024–020. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available

publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CBOE–2024–020 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–08571 Filed 4–22–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99981; File No. SR–CboeEDGX–2024–022]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Short Term Options Series Program in Rule 19.6, Interpretation and Policy .05

April 17, 2024.

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 April 15, 2024, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') 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 Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to amend the Short Term Options Series Program in Rule 19.6, Interpretation and Policy .05. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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 the Short Term Option Series Program in Rule 19.6, Interpretation and Policy .05 (Series of Options Contracts Open for Trading). Specifically, the Exchange proposes to expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (''IWM''), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM.

Currently, Table 1 in Rule 19.6, Interpretation and Policy .05(h), specifies each symbol that qualifies as a Short Term Option Daily Expiration.[5] Today, Table 1 permits the listing and trading of Monday Short Term Option Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[6] The listing and trading of Tuesday and Thursday Short Term Option Daily Expirations would be subject to Rule 19.6, Interpretation and Policy .05.

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (''SPY'') and the INVESCO QQQ TrustSM, Series 1 (''QQQ'') may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[7] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Wednesday Short Term Option Expiration Date'').[8]

In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[9]

The interval between strike prices for the proposed Tuesday and Thursday

[38] 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)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). See Rule 19.6, Interpretation and Policy .05.

[6] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 Rule 19.6, Interpretation and Policy .05(h) from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed pursuant to the Short Term Option Series.

[7] *See* Rule 19.6, Interpretation and Policy .05(h).

[8] *Id.*

[9] Today, IWM may trade on Mondays and Wednesdays, in addition to Fridays, as is the case for all options series.

IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday IWM Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[10] Specifically, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to Rule 19.6, Interpretation and Policy .05(h), with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[11] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[12] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well. With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to monthly option series, Short Term Option Daily Expirations expire in the same week in which monthly option series on the same class expire.[13] Further, as is the case today with other Tuesday and Thursday Short Term Option Daily Expirations, the Exchange would not permit Tuesday and Thursday Short Term Option Daily Expirations to expire on a business day in which monthly options series or Quarterly Options Series expire.[14] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire. The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below table sets forth the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2023 in the options industry.[15] The Exchange notes that during this time period all options exchanges mitigated weekly strike intervals.

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	62.82
Weekly	17.22
LEAP	17.77
Quarterly	2.20

Similar to SPY and QQQ, the Exchange would limit the number of Short Term Option Daily Expirations for IWM to two expirations for Tuesday and Thursday expirations while expanding the Short Term Option Series Program to permit Tuesday, and Thursday expirations for IWM. Expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in IWM will account for the addition of 6.77% of strikes for IWM.[16] With respect to the impact to the Short Term Option Series Program on IWM overall, the impact would be a 20% increase in strikes.[17] With respect to the impact to the Short Term Options Series Program overall, the impact would be a 0.1% increase in strikes.[18] Members will continue to be able to expand hedging tools because all days of the week would be available to permit Members to tailor their investment and hedging needs more effectively in IWM.

NUMBER OF STRIKES—2023

Expiration	Percent of total series (percent)
Monthly	35.13
Weekly	48.30
LEAP	12.87
Quarterly	3.70

Weeklies comprise 48.30% of the total volume of options contracts.[19] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants. The introduction of IWM Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule

[10] *See* Rule 19.6, Interpretation and Policy .05(e).

[11] *See* Rule 19.6, Interpretation and Policy .05(a).

[12] *See* Rule 19.6, Interpretation and Policy .05(a).

[13] *See* Rule 19.6, Interpretation and Policy .05(b).

[14] *See* Rule 19.6, Interpretation and Policy .05(h).

[15] Per Nasdaq ISE, LLC (''Nasdaq ISE''), this information was sourced from The Options Clearing Corporation (''OCC''). The information includes time averaged data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

[16] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[17] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[18] Nasdaq ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024. *See id.*

[19] This table sets forth industry volume. Weeklies comprise 48.30% of volume while only comprising 17.22% of the strikes. Nasdaq ISE sourced this information from OCC. The information includes data for all 17 options markets through December 8, 2023. *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06).

[20] 15 U.S.C. 78f(b).

change is consistent with the Section 6(b)(5)[21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure. In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. The Exchange currently lists SPY and QQQ Tuesday and Thursday Short Term Daily Expirations.[23]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similar to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[24] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on a business day in which monthly options series or Quarterly Options Series expire.[25] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange notes the proposed rule change is substantively the same as a rule change proposed by ISE, which the Commission recently approved.[26]

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. Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on the Exchange.[27] Additionally, as noted above, the Commission recently approved a substantively identical proposal of another exchange.[28] Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30] 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[31] and subparagraph (f)(6) of Rule 19b–4 thereunder.[32]

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] *See* Rule 19.6, Interpretation and Policy .05(h).

[24] *See* Rule 19.6, Interpretation and Policy .05(b).

[25] *See* Rule 19.6, Interpretation and Policy .05(h).

[26] *See* Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

[27] See Rule 19.6, Interpretation and Policy .05(h).

[28] See Securities Exchange Act Release No. 99946 (April 11, 2024) (SR–ISE–2024–06).

[29] 15 U.S.C. 78s(b)(3)(A)(iii).

[30] 17 CFR 240.19b–4(f)(6).

[31] 15 U.S.C. 78s(b)(3)(A)(iii).

[32] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

A proposed rule change filed under Rule 19b–4(f)(6) [33] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[34] the Commission may 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 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[35] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as its competitor exchanges, thus creating competition among Short Term Option Series. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[36]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. 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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2024–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGX–2024–022. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2024–022 and should be submitted on or before May 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Vanessa A. Countryman,

Secretary.

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BILLING CODE 8011–01–P

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6)(iii).

[35] *See supra* note 26.

[36] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[37] 17 CFR 200.30–3(a)(12), (59).

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0658]

OFS SBIC I, LP; Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under section 309 of the Small Business Investment Act of 1958, as amended, and 13 CFR 107.1900 of the Code of Federal Regulations to function as a small business investment company under the Small Business Investment Company license number 02/02–0658 issued to OFS SBIC I, LP, said license is hereby declared null and void.

Bailey Devries,

Associate Administrator, Office of Investment and Innovation, United States Small Business Administration.

[FR Doc. 2024–08579 Filed 4–22–24; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2024–0011]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections, and one new collection for OMB-approval.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833–410–1631, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAmain* by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items. Please reference Docket ID Number [SSA–2024–0011] in your submitted response.

I. The information collection below is pending at SSA. SSA will submit it to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than June 24, 2024. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Partnership Questionnaire—20 CFR 404.1080–404.1082—0960–0025. SSA considers partnership income in determining entitlement to Social Security benefits. SSA uses information from Form SSA–7104 to determine several aspects of eligibility for benefits, including the accuracy of reported partnership earnings; the veracity of a retirement; and lag earnings where SSA needs this information to determine the status of the insured. The respondents are applicants for, and recipients of, Title II Social Security benefits who are reporting partnership earnings.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
SSA–7104 (mailed)	2,154	1	30	1.077	*31.48		***33,904
SSA–7104 (completed in or brought to a field office)	2,154	1	30	1,077	*31.48	**24	***61,040
Totals	4,308			2,154			***94,944

* We based this figure on average the U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm).*
** We based this figure on the average FY 2024 wait times for field offices, based on SSA's current management information data.
*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. There is no actual charge to respondents to complete the application.

2. Medical Source Statement of Ability To Do Work Related Activities (Physical and Mental)—20 CFR 404.1512–404.1513, 416.912–416.913, 404.1517, and 416.917—0960–0662. When a claimant appeals a denied disability claim, SSA may ask the claimant to have a consultative examination at the agency's expense, if the claimant's medical sources cannot, or will not, give the agency sufficient evidence to determine whether the claimant has a disability. The medical providers who perform these consultative examinations provide a statement about the claimant's state of disability. Specifically, these medical source statements determine the work-related capabilities of these claimants. SSA collects the medical data on the HA–1151 and HA–1152 to assess the work-related physical and mental capabilities of claimants who appeal SSA's previous determination on their issue of disability. The respondents are medical sources who provide reports based either on existing medical evidence or on consultative examinations.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HA–1151	5,000	30	15	37,500	*49.07	**1,840,125
HA–1152	5,000	30	15	37,500	*49.07	**1,840,125
Totals	10,000			75,000		**3,680,250

* We based this figure on average medical professionals' salaries, as reported by the U.S. Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes290000.htm*)
** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. There is no actual charge to respondents to complete the application.

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than May 23, 2024. Individuals can obtain copies of these OMB clearance packages by writing to the *OR.Reports.Clearance@ssa.gov.*

1. Representative Availability Portal for Social Security Administration Hearings—20 CFR 404.929, 404.933, 404.1740, 416.1429, 416.1433, 416.1540, 418.1350, 422.203—0960–NEW. As part of the appeals process, claimants can request a hearing with an Administrative Law Judge (ALJ). Approximately 80 percent of claimants have appointed representatives at the hearing level. When the Social Security Administration (SSA) schedules hearings before an ALJ, it usually considers the availability of appointed representatives, if applicable. Appointed representatives may be members of large firms, appearing at hearings nationwide, or may be solo practitioners servicing a specific geographic location or hearing office. In both situations, it is typical for appointed representatives to represent more than one claimant at any given moment; some represent hundreds of claimants at once.

Historically, the process of seeking, tracking, and considering representative availability has been a manual and time-intensive activity. In the past, hearing offices sought representative availability information by contacting each representative individually. More recently, Office of Hearings Operations' Regional Offices representatives collected availability information. Representatives provided Regional Office staff with their hearing availability via telephone or email. However, the process for gathering and considering representative availability was not standardized and varied greatly amongst Regional Offices. The appointed representative community informed SSA they would appreciate a

consistent and standardized electronic process to submit their availability for hearing appearances.

In the Spring of 2023, SSA initiated the Enhanced Representative Availability Process (ERAP) to provide representatives with a more standardized and streamlined process to email their availability for hearings. In the interim, SSA obtained OMB approval to test a new Representative Availability Portal (Portal) to offer the representative community a web-based option to submit their monthly availability to SSA, as per 20 CFR 404.1740(b)(3)(iii) and 416.1540(b)(3)(iii) and in a manner consistent with ERAP. SSA tested the Portal among 11 appointed representative practice groups nationwide. We are currently seeking OMB approval for the national rollout of the Portal, which collects standardized information regarding appointed representative availability for the purpose of scheduling hearings.

SSA plans to roll the Portal out to all appointed representatives registered with the Registration, Appointment and Services for Representatives (RASR) application, other professional representatives who regularly conduct hearing business with SSA but are not registered with RASR, and delegated officials from appointed representative's Designated Scheduling Groups (DSG). A DSG is a representative-identified scheduling group which can include one representative, or multiple representatives. Respondents will need to have a *mySocial Security* account to use the Portal and be registered into the Portal by SSA systems. Respondents who wish to use the Portal, but who are not registered with RASR, or who do not have a Representative ID, must provide SSA systems with the necessary data, including name and SSN, to complete the Portal registration process.

Portal respondents, once registered, are authorized representatives and delegated officials from appointed representatives' DSG. SSA will use the Portal to track availability for hearings for the DSG. Representatives provide hearing availability for the DSG monthly (as described above), and SSA considers the DSG-provided availability when scheduling hearings.

SSA will announce the response window for the Portal each month via a reminder email, approximately ten days prior to the deadline for Portal submissions. Following the submission deadline, the Portal will ''lock,'' and respondents will not be able to submit availability through the Portal at that time. However, SSA has some discretion to approve a request for a late submission or modification and plans to have the capacity to unlock the Portal, when warranted. Portal response options will include DSG group, hearing region, availability during the period of submission, and respondent-preferred case maximums. The Portal will allow SSA to obtain the information we require to schedule hearings for attendees.

If the respondents choose not to submit their availability via the Portal, the option of submitting their availability through email submission (as is the current practice) will remain. If a representative elects not to timely submit any availability via the Portal or email, SSA will schedule their hearings without their input.

We expect use of the Portal will result in receiving consistent structured data from appointed representatives, which will allow for a more streamlined and effective hearing scheduling process. The Portal also meets a longstanding customer-experience request by the representative community, one of SSA's key stakeholders in the process.

The respondents are appointed representatives, and delegated officials from appointed representatives' DSGs who need to submit their availability to SSA for hearings.

Type of Request: Request for a new information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) **	Total annual opportunity cost (dollars) ***
Representative Availability Portal for SSA Hearings	* 3,000	12	36,000	20	12,000	** 84.84	*** 1,018.080

* This figure represents the approximate number of individual representatives registered with RASR who regularly schedule hearings with the agency.

** We based this figure on the mean hourly wage for the average lawyer in the United States as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes231011.htm*).

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. There is no actual charge to respondents to complete the application.

2. Statement of Death by Funeral Director and State Death Match Collections—20 CFR 404.301, 404.310–404.311, 404.316, 404.330–404.341, 404.350–404.352, 404.371, 404.715, 404.720, and 416.912—0960–0142. The death of a beneficiary is an event that terminates the individual's entitlement to Social Security benefits. As regulated, states must furnish death information to SSA to compare to SSA's payment files. SSA employs two modalities for ensuring it efficiently receives accurate information regarding the deaths of SSA-insured workers and beneficiaries: (1) Form SSA–721, Statement of Death by Funeral Director; and (2) the Electronic Death Registration (EDR). SSA operates the State Death Match collections, which includes the EDR process for electronically reporting death records to SSA. The states furnish death certificate information to SSA via a manual registration process (the SSA–721), or via the EDR Registration Process. Both death match processes are automated electronic transfers between the states and SSA. This collection, via paper form SSA–721 or the EDR, allows for the funeral director or funeral home responsible for the individual's burial or cremation to report the death to SSA. SSA uses this information for three purposes: (1) to establish proof of death for the insured worker; (2) to determine if the insured individual was receiving any pre-death benefits SSA needs to terminate; and (3) to ascertain which surviving family member is eligible for the lump-sum death payment or for other death benefits. The respondents for this information collection are funeral directors who handled death arrangements for the insured individuals, and the states' bureaus of vital statistics.

Type of Request: Revision of an OMB-approved information collection.

EDR

Modality of completion	Number of respondents	Frequency of response	Average cost per record request	Estimated total annual burden hours (cost)	Average theoretical hourly cost amount (dollars) **	Total annual opportunity cost (dollars) ***
State Death Match—EDR *	54	3,164,477	$2.77	$473,342,469	** 23.00	*** 72,782,971
States Expected to Become—State Death Match-EDR Within the Next 3 Years *	1	1,247	3.73	4,651	** 23.00	*** 28,681
Totals:	55			473,347,120		*** 72,811,652

* Please note that both of these data matching processes are electronic, and nearly immediate. Therefore, there is only a cost burden, and no hourly burden for the respondent to provide this information.

We estimated the frequency of responses by taking the total number of actual records received for calendar year 2023 for each category and dividing by the number of respondents, per category.

We have 54 States and Jurisdictions currently using EDR. Guam recently showed interest in becoming an EDR site. Estimated sometime mid to late next year 2024.

** We based this figure on the average Records Clerk hourly wages as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes434199.htm*).

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. There is no actual charge to respondents to complete the application.

SSA–721

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) **	Total annual opportunity cost (dollars) ***
SSA–721	437,449	1	4	29,163	$27.90 *	$813,648 **

* We based this figure on average funeral home manager's hourly salary in May 2024, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes394031.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. There is no actual charge to respondents to complete the application.

3. *Retaining Employment and Talent After Injury/Illness Network (RETAIN)—0960–0821.* The SSA and the U.S. Department of Labor (DOL) are conducting the Retaining Employment and Talent After Injury/Illness Network (RETAIN) demonstration. The RETAIN demonstration tests the impact of early intervention strategies that improve stay-at-work/return-to-work (SAW/RTW) outcomes of individuals who experience work disability while employed. We define ''Work disability'' as an injury, illness, or medical condition that has the potential to inhibit or prevent continued employment or labor force participation. SAW/RTW programs succeed by returning injured or ill workers to productive work as soon as medically possible during their recovery process, and by providing interim part-time or light duty work and accommodations, as necessary. We loosely modeled the RETAIN Demonstration Projects after promising programs operating in Washington State, including the Centers of Occupational Health and Education (COHE), the Early Return to Work (ERTW), and the Stay at Work programs.

While these programs operate within the state's workers' compensation system, and are available only to people experiencing work-related injuries or illnesses, the RETAIN Demonstration Projects provide opportunities to improve SAW/RTW outcomes for both occupational and non-occupational injuries and illnesses of people who are employed, or at a minimum in the labor force, when their injury or illness occurs.

The primary goals of the RETAIN Demonstration Projects are:

1. To increase employment retention and labor force participation of individuals who acquire, and/or are at risk of developing, work disabilities; and

2. To reduce long-term work disability among RETAIN service users, including the need for Social Security Disability Insurance and Supplemental Security Income.

The Retain Demonstration aims to validate and expand evidence-based strategies to accomplish these goals. DOL funds intervention approaches and programmatic technical assistance, while SSA funds evaluation support, including technical assistance and the full evaluation for the demonstration. The demonstration consists of two Phases. The first involves the implementation and assessment of cooperative awards to eight states to conduct planning and start-up activities, including the launch of a small pilot demonstration. During Phase 1, SSA provided evaluation-related technical assistance and planning, and conducts evaluability assessments to assess which states' projects would allow for a rigorous evaluation if continued beyond the pilot phase. SSA completed Phase 1 on May 16, 2021. DOL selected a subset of states and continued to Phase 2 full implementation and evaluation on May 17, 2021, which will end in October 2025. During Phase 2, DOL funds the operations and program technical assistance activities for the recommended states, and SSA funds the full set of evaluation activities. The four components of this evaluation, completed during site visits, interviews with RETAIN service users, surveys of RETAIN enrollees, and surveys of RETAIN service providers, include:

- *The participation analysis:* Using RETAIN service user interviews and surveys, this analysis provides insights into which eligible workers choose to participate in the program, in what ways they participate, and how services received vary with participant characteristics. Similarly, it will assess the characteristics of, and if possible, reasons for non-enrollment of non-participants.
- *The process analysis:* Using staff interviews and logs, this analysis produces information about operational features that affect service provision; perceptions of the intervention design by service users, providers, administrators, and other stakeholders; relationships among the partner

organizations; each program's fidelity to the research design; and lessons for future programs with similar objectives.

- *The impact analysis:* This analysis produces estimates of the effects of the interventions on primary outcomes, including employment and Social Security disability applications, and secondary outcomes, such as health and service usage. SSA identifies evaluation designs for each state to generate impact estimates, which could include experimental or non-experimental designs.
- *The cost-benefit analysis:* This analysis assesses whether the benefits of RETAIN justify its costs, conducted from various perspectives, including participants, state and Federal governments, SSA, and society as a whole.

The purpose and proposed use of this information collection is to gather qualitative and quantitative data needed to conduct the analysis. These activities, include (1) surveys of RETAIN enrollees and (2) follow-up interviews with RETAIN service users. The qualitative data collection consists of: (1) semi-structured interviews with program staff and service users; and (2) staff activity logs. Program staff interviews focus on staff's perceptions of the successes and challenges of implementing each states program, while staff activity logs house information on staff's time to inform the benefit-cost analysis. Service user interviews inform SSA's understanding of users' experiences with program services. The quantitative data include SSA's program records and survey data. The survey data collection consists of: (1) two rounds of follow-up surveys, focusing on individual-level outcomes, with enrollees, all of whom who have experienced a disability onset; and (2) two rounds of surveys with RETAIN providers. Respondents learn of the RETAIN program data collection efforts through various outreach methods, including, but not limited to mailings, phone calls, and from other individuals. SSA is constantly reviewing our outreach strategies to ensure maximum exposure and accessibility to the materials. the respondents are staff members selected for staff interviews and staff activity logs, and RETAIN service users, enrollees, and providers.

Type of Request: Request for renewal of an information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
RETAIN 2024 Burden Figures							
Enrollee Survey Round 1 (Respondents)	1,872	1	20	624	* 31.48	** 19	*** 38,311
Enrollee Survey Round 1 (Nonrespondents)	468	1	3	23	* 31.48	** 0	*** 724
Enrollee Survey Round 2 (Respondents)	4,493	1	26	1,947	* 31.48	** 19	*** 106,088
Enrollee Survey Round 2 (Nonrespondents)	1,123	1	3	56	* 31.48	** 0	*** 1,763
Follow-up interviews with service users (Respondents)	20	1	141	47	* 31.48	** 19	*** 1,668
Follow-up interviews with service users (Nonrespondents)	30	1	6	3	* 31.48	** 0	*** 94
Totals	8,006			2,700			*** 148,648
RETAIN 2025 Burden Figures							
Enrollee Survey Round 2 (Respondents)	1,123	1	26	487	* 31.48	** 19	*** 26,538
Enrollee Survey Round 2 (Nonrespondents)	281	1	3	14	* 31.48	** 0	*** 441
Totals	1,404			501			*** 26,979
Grand Total							
Totals	9,410			3,201			*** 175,627

* We based these figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm*).

** We based this figure on average FY 2023 wait times for teleservice centers (approximately 19 minutes per respondent), based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete these tasks; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the tasks. There is no actual charge to respondents to complete the tasks.

Dated: April 17, 2024.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2024–08565 Filed 4–22–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Petition for Authorization to Exceed Mach 1

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

ACTION: Notice of decision to grant an authorization to exceed Mach 1.

SUMMARY: This notice summarizes the petition Boom Supersonic, Inc. submitted to the FAA requesting a special flight authorization as provided for in FAA regulations. The notice also provides for public awareness of FAA's decision to grant Boom Supersonic, Inc.'s request. The FAA is not requesting comments on the petition or the FAA's decision regarding the petition because a special flight authorization petition to exceed Mach 1 follows a separate regulatory process.

DATES: The grant of the special flight authorization to exceed Mach 1 is effective April 7, 2024.

FOR FURTHER INFORMATION CONTACT: Sandy Liu, Office of Environment and Energy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; 202–267–4748, *sandy.liu@faa.gov.*

SUPPLEMENTARY INFORMATION:

Petitioner: Boom Supersonic, Inc.

Applicable Sections of 14 CFR: Sections 91.817 and 91.818.

Description of Relief Sought: Boom Supersonic, Inc. seeks relief to allow certain flight tests to exceed Mach 1.

On March 24, 2023, Boom Supersonic, Inc., Centennial, CO, petitioned the FAA on behalf of Boom Technology, Inc. (''Boom'') to allow Boom to operate a civil aircraft that is expected to exceed Mach 1 speeds during flight testing. Specifically, Boom Supersonic Inc. requested to conduct developmental flight test operations of an experimental aircraft (XB–1) and a chase airplane over Edwards Air Force Base within pre-existing supersonic corridors, located in Los Angeles, Kern, and San Bernardino counties in California. The petitioner requested authorization for up to 20 supersonic test flights over one year. The proposed operations would occur at or above 30,000 ft Mean Sea Level.

On January 12, 2024, the FAA published a notice of availability in the **Federal Register** (89 FR 2471) of an Environmental Assessment (EA) prepared to satisfy National Environmental Policy Act requirements and address the environmental impact of the proposed supersonic operations. The FAA requested comments on the EA. The FAA finalized the EA and issued a Finding of No Significant Impact on February 29, 2024.

The FAA finds the request by the petitioner is well within the intent of 14 CFR 91.818. As such, the FAA has decided to grant this Special Flight Authorization to Exceed Mach 1. Authority to exceed Mach 1 during the testing of the Boom XB–1 experimental aircraft is limited to the conditions and limitations stated in the special flight authorization.

The FAA's decision to grant a special flight authorization in response to Boom Supersonic Inc.'s petition and the applicable environmental review documents are available on FAA's website. The FAA is posting special flight authorization applications, grants of special flight authorizations, and applicable environmental review documents. These documents may be found at: *https://www.faa.gov/about/office_org/headquarters_offices/apl/aee/env_policy/sfa_supersonic.*

Issued in Washington, DC, on April 17, 2024.

Sandy Liu,

Engineer, Noise Division, Office of Environment and Energy, Noise Division (AEE–100).

[FR Doc. 2024–08580 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0054]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: KREWE ZEN (MOTOR); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 23, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2024–0054 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2024–0054 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2024–0054, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel KREWE ZEN is:

Intended Commercial Use of Vessel: Requester intends to offer passenger charters.

Geographic Region Including Base of Operations: Texas, Louisiana, Mississippi, Alabama, Florida. Base of Operations: Galveston, Texas.

Vessel Length and Type: 59′ Sportfish.

The complete application is available for review identified in the DOT docket

as MARAD 2024–0054 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2024–0054 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08618 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0058]

Coastwise Endorsement Eligibility Determination for a Foreign-built Vessel: MEMORY MAKER (MOTOR); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 23, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2024–0058 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2024–0058 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2024–0058, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel MEMORY MAKER is:

Intended Commercial Use of Vessel: Requester intends to offer passenger sightseeing and pleasure cruises on Florida's gulf coast.

Geographic Region Including Base of Operations: Florida. Base of Operations: Sarasota, FL.

Vessel Length and Type: 44′ Power catamaran.

The complete application is available for review identified in the DOT docket as MARAD 2024–0058 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel

in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2024–0058 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08617 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0055]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: PAZ (MOTOR); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 23, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2024–0055 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2024–0055 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2024–0055, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel PAZ is:

Intended Commercial Use of Vessel: Requester intends to offer passenger charters in Florida.

Geographic Region Including Base of Operations: Florida. Base of Operations: Palm Beach Gardens, Florida.

Vessel Length and Type: 52′ Sunseeker.

The complete application is available for review identified in the DOT docket as MARAD 2024–0055 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2024–0055 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08616 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0057]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ANDROMEDA (MOTOR); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 23, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2024–0057 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2024–0057 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2024–0057, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ANDROMEDA is:

Intended Commercial Use of Vessel: Requester intends to offer passenger charters.

Geographic Region Including Base of Operations: Maine, Massachusetts, Rhode Island, New York, Connecticut, Florida. Base of Operations: Watch Island, RI.

Vessel Length and Type: 62′ Catamaran

The complete application is available for review identified in the DOT docket as MARAD 2024–0057 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected

on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2024–0057 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08620 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2024–0056]

Coastwise Endorsement Eligibility Determination for a Foreign-Built Vessel: ALANA KAI (MOTOR); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to issue coastwise endorsement eligibility determinations for foreign-built vessels which will carry no more than twelve passengers for hire. A request for such a determination has been received by MARAD. By this notice, MARAD seeks comments from interested parties as to any effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. Information about the requestor's vessel, including a brief description of the proposed service, is listed below.

DATES: Submit comments on or before May 23, 2024.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2024–0056 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Search MARAD–2024–0056 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is U.S. Department of Transportation, MARAD–2024–0056, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, or to submit comments that are confidential in nature, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Patricia Hagerty, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–461, Washington, DC 20590. Telephone: (202) 366–0903. Email: *patricia.hagerty@dot.gov.*

SUPPLEMENTARY INFORMATION: As described in the application, the intended service of the vessel ALANA KAI is:

Intended Commercial Use of Vessel: Requester intends to offer passenger sunset cruises.

Geographic Region Including Base of Operations: Hawaii. Base of Operations: Honolulu, HI.

Vessel Length and Type: 67.4′ Motor.

The complete application is available for review identified in the DOT docket as MARAD 2024–0056 at *https://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the employment of the vessel in the coastwise trade to carry no more than 12 passengers will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, MARAD will not issue an approval of the vessel's coastwise endorsement eligibility. Comments should refer to the vessel name, state the commenter's interest in the application, and address the eligibility criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *https://www.regulations.gov,* keyword search MARAD–2024–0056 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit the information you claim to be confidential commercial information by email to *SmallVessels@dot.gov.* Include in the email subject heading ''Contains Confidential Commercial Information'' or ''Contains CCI'' and state in your submission, with specificity, the basis for any such confidential claim highlighting or denoting the CCI portions. If possible, please provide a summary of your submission that can be made available to the public.

In the event MARAD receives a Freedom of Information Act (FOIA) request for the information, procedures described in the Department's FOIA regulation at 49 CFR 7.29 will be followed. Only information that is ultimately determined to be confidential under those procedures will be exempt from disclosure under FOIA.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). For information on DOT's compliance with the Privacy Act, please visit *https://www.transportation.gov/privacy.*

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08619 Filed 4–22–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley Smith, 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 Compliance, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*ofac.treasury.gov*).

Notice of OFAC Action(s)

On March 11, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. ABU SHANAB, William (Arabic: ويليام أبة شنب) (a.k.a. ABU SHANAB, William Mahmud), Sidon, Lebanon; DOB 1985; nationality Lebanon; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: HAMAS).

   Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism," 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (E.O. 13224, as amended), for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. AL-KAHLUT, Hudhayfa Samir 'Abdallah (Arabic: حذيفة سمير عبدالله الكحلوت) (a.k.a. AL-KAHLOUT, Hudayfa Samir Abdullah (Arabic: حوديفه سمير عبدالله الكحلوت); a.k.a. AL-KAHLUT, Hudifah Samir 'Abdallah), Gaza; DOB 11 Feb 1985; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 800894164 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. 'AZZAM, Khalil Muhammad (a.k.a. AZAM, Khalil Mouhamad; a.k.a. AZZAM, Khalil Mohammed; a.k.a. 'AZZAM, Khalil Muhammad Khalil (Arabic: خليل محمد خليل عزام)), Tripoli, Lebanon; DOB 01 Jan 1968; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: HAMAS).

   Designated pursuant to section 1(a)(iii)(A) of (E.O. 13224, as amended for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

4. FARHAT, Bara'a Hasan (Arabic: براء حسن فرحات), Sidon, Lebanon; DOB 1988; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: HAMAS).

   Designated pursuant to section 1(a)(iii)(A) E.O. 13224, as amended for having acted or purported to act for or on behalf of, directly or indirectly, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: April 12, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–08667 Filed 4–22–24; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, 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 Enforcement, Compliance and Analysis, 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 Actions

On April 18, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. AL–TAF, Ali Asghar (a.k.a. ATTAF GHOLAMHOSEIN, Ali Asghar), Shahin Shahr, Iran; DOB 21 Dec 1978; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 2529687692 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism'' (E.O. 13224), 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions To Combat Terrorism,'' 84 FR 48041, 3 CFR, 2019 Comp., p. 356 (E.O. 13224, as amended) for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

2. ARAMBUNEZHAD, Hasan (a.k.a. HABIBI, Hasan), Iran; DOB 23 Sep 1975; POB Varamin, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 6589640386 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC; Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. AZIZKHANI, Esma'il, Sepahan City, Iran; DOB 07 Oct 1981; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 1285006501 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. DEHGHAN, Majid, Iran; DOB 22 Sep 1988; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0083115234 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: FATEH ASEMAN SHARIF COMPANY).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, FATEH ASEMAN SHARIF COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

5. EBRAHIMI FORUSHANI, Hamid Hajji (a.k.a. EBRAHIMI FORUSHAN, Hamid Hajji), Esfahan, Iran; DOB 08 Sep 1980; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 1141913534 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

6. FATEHI, Mohammad Sadegh, Iran; DOB 21 Sep 1982; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 1288345801 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

7. MOSHKANI, Abolfazl Ramazanzadeh (a.k.a. MASHKANI, Abolfazl Ramezanzadeh; a.k.a. REZA'I', Abolfazl), Tehran, Iran; DOB 11 Jun 1988; POB Kashan, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 1263617549 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

8. NAGHNEH, Mehdi Ghaffari (a.k.a. NAQNAH, Mahdi Ghaffari), Shar-e Kord, Iran; DOB 01 Mar 1991; POB Borujen, Iran; nationality Iran;

Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 4640070391 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

9. NAHAR DANI, Reza (a.k.a. NAHAR DANI, Ali Reza), Tehran, Iran; DOB 11 Jun 1986; POB Tehran, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0082970165 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

10. RAMSHEH, Ali Reza Nurian, Iran; DOB 25 May 1967; alt. DOB 20 Jun 1967; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0938665847 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

11. SARTAJI, Abbas (a.k.a. HEDAYAT, Reza; a.k.a. SARTAJI, Abas), Tehran, Iran; DOB 23 Aug 1983; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Passport M51368656 (Iran); National ID No. 6039648112 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

12. TURANLU, Mohsen Sayyadi (a.k.a. TURANLU, Muhsin Sayyadi), Iran; DOB 23 Aug 1979; POB Shiravan, Iran; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0827989709 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: KIMIA PART SIVAN COMPANY LLC).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, KIMIA PART SIVAN COMPANY LLC. a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

13. ZAVARAKI, Hadi Jamshidi (a.k.a. KAMALI, Hadi), Karaj, Iran; DOB 23 Apr 1986; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0082700958 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE).

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)-QODS FORCE, a person whose property and interests in property are blocked pursuant to E.O. 13224.

14. ABUTALEBI, Mohammad Sadegh (a.k.a. ABOUTALEBI, Mohammad Sadegh; a.k.a. ABUTALEBI, Mohammad Sadiq), Qom, Iran; DOB 22 Jun 1964; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0530439441 (Iran) (individual) [NPWMD] [IRGC] [IFSR] (Linked To: OJE PARVAZ MADO NAFAR COMPANY).

Designated pursuant to section 1(a)(iv) of Executive Order 13382 of June 28, 2005, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters,'' 70 FR 38567, 3 CFR, 2005 Comp., p. 170 (E.O. 13382), for acting or purporting to act for or on behalf of, directly or indirectly, OJE PARVAZ MADO NAFAR COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13382.

15. ABUTALEBI, Ali Asghar (a.k.a. ABOUTALEBI, Ali Asghar; a.k.a. ABU TALEBI, Ali Asghar), Qom, Iran; DOB 10 Aug 1961; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0530657491 (Iran) (individual) [NPWMD] [IRGC] [IFSR] (Linked To: OJE PARVAZ MADO NAFAR COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, OJE PARVAZ MADO NAFAR COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13382.

16. NAJAFI, Ali Habibi (a.k.a. HABIBI, Ali), Tehran, Iran; DOB 25 Dec 1977; nationality Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; National ID No. 0060598298 (Iran) (individual) [NPWMD] [IFSR] (Linked To: ASEMAN PISHRANEH CO. LTD)

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ASEMAN PISHRANEH CO. LTD, a person whose property and interests in property are blocked pursuant to E.O. 13382.

Entities

1. ASEMAN PISHRANEH CO. LTD (a.k.a. ASEMAN PISHRANEH ENGINEERING SERVICES LIMITED LIABILITY COMPANY; a.k.a. SKY PROPULSION ENGINEERING RESEARCH AND SERVICES CONSULTING COMPANY; a.k.a. SKY PROPULSION ENGINEERING SERVICES COMPANY), Kilometer 13 of Shahid Babaei Highway, Intersection of Telo Road (Northwest Side), Aerospace Complex (Sepehr Airport), Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; Organization Established Date 14 Apr 1999; National ID No. 10101922753 (Iran); Registration Number 149432 (Iran) [NPWMD] [IFSR] (Linked To: PARAVAR PARS COMPANY)

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, PARAVAR PARS COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. FATEH ASEMAN SHARIF COMPANY (a.k.a. FATEH ASEMAN SHARIF KNOWLEDGE BASED COMPANY), 18th District, 5 Kilometers of Fatah Highway, Nord Blvd., Tehran, Iran; Additional Sanctions Information—Subject to Secondary Sanctions; National ID No. 10320891651 (Iran) [SDGT] [IRGC] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS).

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended,

for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ISLAMIC REVOLUTIONARY GUARD CORPS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: April 18, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–08633 Filed 4–22–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Low Income Taxpayer Clinic Grant Program; Availability of 2025 Grant Application Package

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Solicitation of grant applications.

SUMMARY: This document contains a notice that the IRS has provided a grant opportunity in *www.grants.gov* for organizations interested in applying for a Low Income Taxpayer Clinic (LITC) matching grant. The IRS is authorized to award multi-year LITC grants not to exceed three years. (Organizations currently participating in the LITC grant program that are submitting a Non-Competing Continuation Request for continued funding for 2025 must do so electronically at *www.grantsolutions.gov*). Grants may be awarded for the development, expansion, or continuation of programs providing qualified services to eligible taxpayers. Grant funds may be awarded for start-up expenditures incurred by new clinics during 2025. The budget and the period of performance for the grant will be January 1, 2025–December 31, 2025. The application period runs from April 22, 2024, through June 12, 2024.

DATES: All applications and requests for continued funding for the 2025 grant year must be filed electronically by 11:59 p.m. (Eastern Time) on June 12, 2024. All organizations must use the funding number of TREAS–GRANTS–042025–001, and the Catalog of Federal Domestic Assistance program number is 21.008, see *www.sam.gov.* The IRS is scheduling two optional webinars, Session One on April 25, and Session Two on May 7, 2024, to cover the full application process. See *www.irs.gov/advocate/low-income-taxpayer-clinics* for complete details, including posted materials and any changes to the date and time.

FOR FURTHER INFORMATION CONTACT: Karen Tober at (202) 317–4700 (not a toll-free number) or by email at *karen.tober@irs.gov.* The IRS office that provides oversight of the LITC grant program is the LITC Program Office, located at: IRS, Taxpayer Advocate Service, LITC Grant Program Administration Office, TA:LITC, 1111 Constitution Avenue NW, Room 1034, Washington, DC 20224. Copies of the *2024 Grant Application Package and Guidelines,* IRS Publication 3319 (Rev. 5–2024), can be downloaded from the IRS internet site at *https://www.taxpayeradvocate.irs.gov/about-us/litc-grants/* or ordered by calling the IRS Distribution Center toll-free at 1–800–829–3676. See *https://youtu.be/6kRrjN-DNYQ* for a short video about the LITC Program. Note: To assist organizations in applying for funding, the ''Reminders and Tips for Completing Form 13424–M'' available at *https://www.taxpayeradvocate.irs.gov/about-us/litc-grants* will include instructions for which questions an organization should complete if requesting funding only for the English as a second language (ESL) Education Pilot Program described in this notice.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 26 U.S.C. 7526, the IRS will annually award up to $6,000,000 (unless otherwise provided by specific Congressional appropriation) to qualified organizations, subject to the limitations in the statute. For FY 2024, Congress has provided overall LITC grant funding of $28 million and has authorized funding of up to $200,000 per clinic. The President's FY 2025 budget request proposes an overall LITC grant funding level of $26 million and a continuation of the $200,000 per-clinic funding cap. In light of the President's budget request and the uncertain timeline for final congressional action, the IRS will allow applicants to request up to $200,000 for the 2025 grant year. The IRS will also continue the ESL Education Pilot Program that was rolled out as part of the February 2023 supplemental funding opportunity. If for FY 2025 Congress significantly reduces the overall LITC grant funding level or reduces the per-clinic funding cap, the IRS will adjust each grant recipient's award to reflect any limitations in place at that time.

For an applicant proposing to provide tax controversy representation, at least 90 percent of the taxpayers represented by the clinic must have incomes which do not exceed 250 percent of the poverty level as determined under criteria established by the Director of the Office of Management and Budget. See 89 FR 2961–2963 (January 17, 2024). In addition, the amount in controversy for the tax year to which the controversy relates generally cannot exceed the amount specified in Internal Revenue Code (IRC) section 7463 ($50,000) for eligibility for special small tax case procedures in the United States Tax Court. IRC section 7526(c)(5) requires clinics to provide dollar-for-dollar matching funds, which may consist of funds from other sources or contributions of volunteer time. See IRS Pub. 3319 for additional details. An applicant who is planning to operate a program to inform ESL taxpayers about their taxpayer rights and responsibilities must have either a volunteer or a staff member designated as a Qualified Tax Expert, generally an attorney, enrolled agent or certified public accountant, to review and approve all educational material.

Mission Statement

Low Income Taxpayer Clinics ensure the fairness and integrity of the tax system for taxpayers who are low-income or ESL by providing *pro bono* representation on their behalf in tax disputes with the IRS; educating them about their rights and responsibilities as taxpayers; and identifying and advocating for issues that impact low-income and ESL taxpayers.

Expansion of the Type of Qualified Services an Organization Can Provide Through Implementation of ESL Education Pilot

IRC section 7526(b)(1)(A) authorizes the IRS to award grants to organizations that represent low-income taxpayers in controversies before the IRS or provide education to ESL taxpayers regarding their taxpayer rights and responsibilities.

To achieve maximum access to justice for low-income and ESL taxpayers, the IRS has expanded the eligibility criteria for a grant by removing the requirement for eligible organizations to provide direct controversy representation. Pursuant to the ESL Education Pilot Program started in 2023 and continued through 2025, a grant may be awarded to an organization to operate a program to inform ESL taxpayers about their taxpayer rights and responsibilities under the IRC without the requirement to also provide tax controversy representation to low-income taxpayers. See IRS Pub. 3319 for examples of what constitutes a ''clinic.'' Applicants

should note clearly on their applications their intent to apply for the Pilot Program and should carefully follow special instructions that will be supplied for completing the application for the Pilot Program.

Selection Consideration

Despite the IRS's efforts to foster parity in availability and accessibility in choosing organizations receiving LITC matching grants and the continued increase in clinic services nationwide, there remain communities that are underserved by clinics. The states of Hawaii, Kansas, Nevada, North Dakota, South Dakota, and West Virginia and the territory of Puerto Rico currently do not have an LITC. In addition, two states—Florida and Montana—have only partial coverage. The uncovered counties in Florida are Citrus, Hamilton, Hernando, Lafayette, Madison, Nassau, St. Johns, Sumter, Suwannee, Taylor, Brevard, Lake, Orange, Osceola, Seminole, and Volusia. The uncovered counties in Montana and are Blaine, Broadwater, Carbon, Carter, Custer, Daniels, Dawson, Deer Lodge, Fallon, Fergus, Flathead, Garfield, Golden Valley, Granite, Jefferson, Judith Basin, Lincoln, Madison, McCone, Mineral, Missoula, Musselshell, Petroleum, Phillips, Pondera, Powder River, Powell, Prairie, Richland, Sanders, Sheridan, Stillwater, Sweet Grass, Toole, Treasure, Valley, Wheatland, and Wibaux.

Although each application for the 2025 grant year will be given due consideration, the IRS is especially interested in receiving applications from organizations providing services in these underserved geographic areas. For organizations that intend to refer low-income taxpayers involved in controversies with the IRS to other qualified representatives rather than providing representation directly to low-income taxpayers, priority will be given to established organizations that can help provide coverage to underserved geographic areas. For the ESL Education Pilot Program, special consideration will be given to established organizations with existing community partnerships that can swiftly implement and deliver services to the target audiences.

As in prior years, the IRS will consider a variety of factors in determining whether to award a grant, including: (1) the number of taxpayers who will be assisted by the organization, including the number of ESL taxpayers in that geographic area; (2) the existence of other LITCs assisting the same population of low-income and ESL taxpayers; (3) the quality of the program offered by the organization, including the qualifications of its administrators and qualified representatives, and its record in providing services to low-income taxpayers; (4) the quality of the organization, including the reasonableness of the proposed budget; (5) the organization's compliance with all Federal tax obligations (filing and payment); (6) the organization's compliance with all Federal nontax monetary obligations (filing and payment); (7) whether debarment or suspension (31 CFR part 19) applies or whether the organization is otherwise excluded from or ineligible for a Federal award; and (8) alternative funding sources available to the organization, including amounts received from other grants and contributors and the endowment and resources of the institution sponsoring the organization.

For programs where all or the majority of cases will be placed with volunteers, we will also consider the following: (1) the quality of the representatives (attorneys, certified public accountants, or enrolled agents who have agreed to accept taxpayer referrals from an LITC and provide representation or consultation services free of charge); and (2) the ability of the organization to monitor referrals and ensure that the *pro bono* representatives are handling the cases properly, including taking timely case actions and ensuring services are offered for free or a nominal fee.

Applications and requests for continued funding that pass the eligibility screening process will then be subject to technical review. An organization submitting a request for continued funding for the second or third year of a multi-year grant will be required to submit an abbreviated Non-competing Continuation Request and will be subject to a streamlined screening process. Details regarding the scoring process can be found in Publication 3319. The final funding decisions are made by the National Taxpayer Advocate. The costs of preparing and applying are the responsibility of each applicant. Applications may be released in response to Freedom of Information Act requests after any necessary redactions are made. Therefore, applicants must not include any individual taxpayer information. The IRS will notify each applicant in writing once funding decisions have been made.

Erin M. Collins,

National Taxpayer Advocate.

[FR Doc. 2024–08641 Filed 4–22–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Low Income Taxpayer Clinic Grant Program; Availability of 2025 Grant Application Package

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Solicitation of grant applications.

SUMMARY: This document contains a notice that the IRS has provided a grant opportunity in *www.grants.gov* for organizations interested in applying for a Low Income Taxpayer Clinic (LITC) matching grant. The IRS is authorized to award multi-year LITC grants not to exceed three years. (Organizations currently participating in the LITC grant program that are submitting a Non-Competing Continuation Request for continued funding for 2025 must do so electronically at *www.grantsolutions.gov*). Grants may be awarded for the development, expansion, or continuation of programs providing qualified services to eligible taxpayers. Grant funds may be awarded for start-up expenditures incurred by new clinics during 2025. The budget and the period of performance for the grant will be January 1, 2025–December 31, 2025. The application period runs from April 22, 2024, through June 12, 2024.

DATES: All applications and requests for continued funding for the 2025 grant year must be filed electronically by 11:59 p.m. (Eastern Time) on June 12, 2024. All organizations must use the funding number of TREAS–GRANTS–042025–001, and the Catalog of Federal Domestic Assistance program number is 21.008, see *www.sam.gov.* The IRS is scheduling two optional webinars, Session One on April 25, and Session Two on May 7, 2024, to cover the full application process. See *www.irs.gov/advocate/low-income-taxpayer-clinics* for complete details, including posted materials and any changes to the date and time.

FOR FURTHER INFORMATION CONTACT: Karen Tober at (202) 317–4700 (not a toll-free number) or by email at *karen.tober@irs.gov.* The IRS office that provides oversight of the LITC grant program is the LITC Program Office, located at: IRS, Taxpayer Advocate Service, LITC Grant Program Administration Office, TA:LITC, 1111 Constitution Avenue NW, Room 1034, Washington, DC 20224. Copies of the *2024 Grant Application Package and Guidelines,* IRS Publication 3319 (Rev. 5–2024), can be downloaded from the

IRS internet site at *https://www.taxpayeradvocate.irs.gov/about-us/litc-grants/* or ordered by calling the IRS Distribution Center toll-free at 1–800–829–3676. See *https://youtu.be/6kRrjN-DNYQ* for a short video about the LITC Program. Note: To assist organizations in applying for funding, the ''Reminders and Tips for Completing Form 13424–M'' available at *https://www.taxpayeradvocate.irs.gov/about-us/litc-grants* will include instructions for which questions an organization should complete if requesting funding only for the English as a second language (ESL) Education Pilot Program described in this notice.

SUPPLEMENTARY INFORMATION:

Background

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Although each application for the 2025 grant year will be given due consideration, the IRS is especially interested in receiving applications from organizations providing services in these underserved geographic areas. For organizations that intend to refer low-income taxpayers involved in controversies with the IRS to other qualified representatives rather than providing representation directly to low-income taxpayers, priority will be given to established organizations that can help provide coverage to underserved geographic areas. For the ESL Education Pilot Program, special consideration will be given to established organizations with existing community partnerships that can swiftly implement and deliver services to the target audiences.

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Erin Collins,

National Taxpayer Advocate.

[FR Doc. 2024–08615 Filed 4–22–24; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

Notice of Meeting: Cooperative Studies Scientific Evaluation Committee

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. Ch. 10, that the Cooperative Studies Scientific Evaluation Committee (CSSEC) will hold its virtual meeting on May 23, 2024, via MS Teams from 10 a.m.–4 p.m. EST.

The Committee provides expert advice on VA cooperative studies, multi-site clinical research activities and policies related to conducting and managing these efforts. The session will be open to the public for the first 2 hours of the meeting (approximately) for the discussion of administrative matters and the general status of the program. The remaining portion of the meeting will be closed to the public for the Committee's review, discussion and evaluation of future research and development applications.

During the closed portion of the meeting, the Committee's discussions and recommendations will address the qualifications of the personnel conducting the studies, and staff and consultant critiques of research proposals and similar documents. Premature disclosure of this research information to the public could significantly obstruct implementation of approved research activities. As provided by Public Law 92–463 subsection 10(d), and amended by Public Law 94–409, closing the Committee meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

The Committee will accept oral comments from the public during a 30-minute public comment period in the open portion of the meeting. Individual stakeholders will be afforded up to 3 minutes to express their comments. Members of the public who wish to attend the open teleconference should call 872–701–0185, conference ID 481 139 269#. Those who plan to attend or would like additional information should contact David Burnaska, Program Manager, Cooperative Studies Program (14RD), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at *David.Burnaska@va.gov.* Those wishing to submit written comments may send them to Mr. Burnaska at the same address and email.

Dated: April 17, 2024.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–08566 Filed 4–22–24; 8:45 am]

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FEDERAL REGISTER

Vol. 89 Tuesday,
No. 79 April 23, 2024

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, et al.

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 460

Office of the Secretary

[CMS–4201–F3 and CMS–4205–F]

RINs 0938–AV24 and 0938–AU96

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)

AGENCY: Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will 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, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D–SNPs), utilization management, network adequacy, and other programmatic areas. This final rule also codifies existing sub-regulatory guidance in the Part C and Part D programs.

DATES: *Effective date:* These regulations are effective June 3, 2024.

Applicability dates: The provisions in this rule are applicable to coverage beginning January 1, 2025, except as otherwise noted. The updates to marketing and communication provisions at §§ 422.2267(e)(34), 422.2274, and 423.2274 are applicable for all contract year 2025 marketing and communications beginning October 1, 2024. The updated provisions at §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) are applicable for all contract year 2026 marketing and communications beginning September 30, 2025, however, at plan option for contract year 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i).

Sections 422.111(l) and 423.530 are applicable beginning January 1, 2026. This final rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process, the appeals process for quality bonus payment determination at § 422.260, weighting of new Part C and D Star Ratings measures at §§ 422.166(e)(2) and 423.186(e)(2), and the rule for Part C and D Star Ratings non-substantive measure updates at §§ 422.164(d) and 423.184(d) applicable 60 days after the date of publication. The use and release of risk adjustment data provisions at §§ 422.310(f)(1)(vi), 422.310(f)(1)(vii), and 422.310(f)(3)(v) are applicable 60 days after the date of publication.

FOR FURTHER INFORMATION CONTACT:

Carly Medosch, (410) 786–8633—General Questions.

Naseem Tarmohamed, (410) 786–0814—Part C and Cost Plan Issues.

Lucia Patrone, (410) 786–8621—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeal Issues.

Kelley Ordonio, (410) 786–3453—Parts C and D Payment Issues.

Hunter Coohill, (720) 853–2804—Enforcement Issues.

Lauren Brandow, (410) 786–9765—PACE Issues.

Sara Klotz, (410) 786–1984—D–SNP Issues.

Joe Strazzire, (410) 786–2775—RADV Audit Appeals Issues.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings Issues.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Programs of All-Inclusive Care for the Elderly (PACE). This final rule includes a number of new policies that will improve these programs beginning with contract year 2025 and will codify existing Part C and Part D sub-regulatory guidance.

Additionally, this final rule will implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- The Consolidated Appropriations Act (CAA), 2023.

2. Summary of the Major Provisions

a. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria

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).

Through this final rule, CMS establishes improved targeting criteria for the Part D MTM program that will help ensure more consistent, equitable, and expanded access to MTM services. After consideration of the comments received, we are finalizing proposed changes to the MTM eligibility criteria with modifications that are effective for January 1, 2025, as follows:

We are finalizing the provision at § 423.153(d)(2)(iii) that Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of this provision at § 423.153(d)(2)(iii), we are codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS, for a total of 10 core chronic diseases. The 10 core chronic diseases are: (1) Alzheimer's disease; (2) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis); (3) Chronic congestive heart failure (CHF); (4) Diabetes; (5) Dyslipidemia; (6) End-stage renal disease (ESRD); (7) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (8) Hypertension; (9) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and (10) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders). Sponsors retain the flexibility to target

additional chronic diseases beyond those codified as core chronic diseases.

We are not finalizing the proposal at § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from eight to five for Contract Year 2025. At this time, we are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs as eight at § 423.153(d)(2)(i)(B). Part D sponsors will maintain the flexibility to set a lower threshold (a number between two and eight Part D drugs) for targeting beneficiaries taking multiple Part D drugs. We may consider revisiting this or similar policies in future rulemaking.

We are finalizing the provision at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs in their targeting criteria with minor modifications to the regulatory text to clarify that sponsors must include all Part D maintenance drugs and to provide flexibility for sponsors to include all Part D drugs in their targeting criteria. However, sponsors will not be permitted to limit the Part D maintenance drugs included in MTM targeting criteria to specific Part D maintenance drugs or drug classes. We are also finalizing the requirement at § 423.153(d)(2)(iv) that, for the purpose of identifying Part D maintenance drugs, plans must rely on information in a widely accepted, commercially or publicly available drug information database.

We are finalizing the provision at § 423.153(d)(2)(i)(C) with modification to set the MTM cost threshold at the average cost of eight generic drugs, as defined at § 423.4. CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

We are also codifying longstanding guidance at § 423.153(d)(1)(vii)(B)(2) to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment. We are also finalizing other technical changes at § 423.153(d)(1)(vii)(B)(1)(i) to clarify that the CMR must include an interactive consultation that is conducted in person or via synchronous telehealth.

b. Improving Access to Behavioral Health Care Providers

We are finalizing regulatory changes that will improve access to behavioral health care by adding a new behavioral health provider specialty to our MA network adequacy standards. Specifically, we are finalizing requirements to add a new facility-specialty type to the existing list of facility-specialty types evaluated as part of network adequacy requirements and reviews. The new facility-specialty type, ''Outpatient Behavioral Health,'' will be included in network adequacy evaluations and can include providers of various types: Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers, Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities, including addiction medicine physicians, other providers. Other providers may include nurse practitioners (NPs), physician assistants (PAs) and Clinical Nurse Specialists (CNSs), who furnish addiction medicine and behavioral health counseling or therapy services and meet other specific criteria. Beginning January 1, 2024, MFTs and MHCs were eligible to enroll in Medicare and start billing for services due to the new statutory benefit category established by the Consolidated Appropriations Act (CAA) 2023. We aim to strengthen network adequacy requirements and improve beneficiary access to behavioral health services and providers by expanding our network adequacy evaluation requirements for MA organizations.

To address concerns that NPs, PAs, and CNSs might lack the necessary skills, training, or expertise to effectively address the behavioral health needs of enrollees and that the absence of criteria for incorporating these provider types could result in the creation of ''ghost networks'' (where providers may be listed in a provider directory without actively treating patients for behavioral health), we are also adopting specific criteria that MA organizations must use to determine when an NP, PA or CNS can be considered part of a network to meet the Outpatient Behavioral Health network adequacy standard. MA organizations must independently verify that the provider has furnished or will furnish such services to 20 patients within a recent 12-month period using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

c. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)

Third-Party Marketing Organizations (TPMOs) are selling and reselling beneficiary contact information to skirt existing CMS rules that prohibit cold calling so they can aggressively market MA and Part D Plans. Beneficiaries are unaware that by placing a call or clicking on a generic-looking web-link they are unwittingly agreeing and providing consent for their personal contact information to be collected and sold to other entities for future marketing activities. As a result, we are finalizing requirements to prohibit personal beneficiary data collected by TPMOs for marketing or enrolling a beneficiary into an MA or Part D plan to be shared with other TPMOs, unless prior express written consent is given by the beneficiary. Furthermore, we are finalizing a one-to-one consent structure where TPMOs must obtain prior express written consent through a clear and conspicuous disclosure for each TPMO that will be receiving the beneficiary's data. This provision is designed to address complaints we have received from beneficiaries and their advocates and caregivers about receiving harassing and unwanted phone and email solicitations from individuals attempting to enroll them in MA and Part D plans. This final rule protects beneficiaries against unwanted calls, texts, email solicitations, and other contacts, while still ensuring that beneficiaries have control over their personal data and can connect with the TPMOs they would like to speak with, creating a more transparent and safer environment for beneficiaries to find the plan that best fits their health needs.

d. Establish Guardrails for Agent and Broker Compensation

Section 1851(j) of the Act requires that CMS develop guidelines to ensure that the use of agent and broker compensation creates incentives to enroll individuals in the MA plan that is intended to best meet their health care needs. To that end, for many years CMS has set upper limits on the amount of compensation agents and brokers can receive for enrolling Medicare beneficiaries into MA and PDP plans. We have learned, however, that many MA and PDP plans, as well as third-party entities with which they contract (such as Field Marketing Organizations (FMOs)) have structured payments to agents and brokers that allow for separate payments for these agents and brokers and have the effect of circumventing compensation caps. We also note that that these separate payments appear to be increasing. In this rule, we are finalizing requirements that will generally prohibit contract terms between MA organizations and agents, brokers or other TPMOs that may interfere with the agent's or broker's ability to objectively assess and

recommend the plan that best fits a beneficiary's health care needs; set a single, increased compensation rate for all plans to be updated annually; revise the scope of items and services included within agent and broker compensation; and eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We are also making conforming edits to the Part D agent broker compensation rules at § 423.2274. Collectively, we believe the impact of these changes will better align with statutory requirements to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the plan that best fits a beneficiary's health care needs. Further, such changes align with the Biden-Harris Administration's commitment to promoting fair, open, and competitive markets and ensuring beneficiaries can make fully informed choices among a robust set of health insurance options.

e. Special Supplemental Benefits for the Chronically Ill (SSBCI)

We are finalizing regulatory changes that will help ensure that SSBCI items and services offered by MA plans are appropriate and meet applicable statutory and regulatory standards, including that the SSBCI items and services are reasonably expected to improve or maintain the health or overall function of chronically ill enrollees. First, we are finalizing requirements that, by the date on which it submits its bid to CMS, an MA organization must establish a bibliography of relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Second, we are clarifying in the regulation that an MA plan must follow its written policies based on objective criteria for determining an enrollee's eligibility for an SSBCI when making such eligibility determinations. Third, we are requiring that the MA plan document both denials and approvals of SSBCI eligibility. Additionally, we are codifying CMS's authority to review and deny approval of an MA organization's bid if the MA organization has not demonstrated, through relevant acceptable evidence, that its proposed SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Finally, we are codifying CMS's authority to review SSBCI offerings annually for compliance, considering the evidence available at the time. We believe these revisions to § 422.102(f) will better ensure that the benefits offered as SSBCI are reasonably expected to improve or maintain the health or overall function of the chronically ill enrollee while also guarding against the use of MA rebate dollars for SSBCI that are not supported by acceptable evidence.

The new SSBCI requirements regarding creation of a bibliography and documentation of SSBCI eligibility for enrollees will apply to plans beginning with the CY2025 bid process. The codification of other SSBCI requirements regarding plans' obligation to follow written SSBCI eligibility policies, and our authority to decline to accept a bid if the MA organization has not demonstrated that its proposed SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee do not represent a change in policy and CMS will continue in practice during the CY2025 bid process and in subsequent years.

In addition, we are finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility criteria. We are modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned. Specifically, we are requiring that the SSBCI disclaimer list the relevant chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization. The MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because other eligibility and coverage criteria also apply. We are also finalizing specific font and reading pace parameters for the SSBCI disclaimer in print, television, online, social media, radio, other voice-based ads, and outdoor advertising (including billboards). Finally, we are requiring that MA organizations include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We believe that imposing these new SSBCI disclaimer requirements will help to ensure that the marketing of and communication about these benefits is not misleading or potentially confusing to enrollees who rely on these materials to make enrollment decisions.

f. Mid-Year Enrollee Notification of Available Supplemental Benefits

In addition, over the past several years, the number of MA plans offering supplemental benefits has increased. The benefits offered are broader in scope and variety and we are seeing an increasing amount of MA rebate dollars directed towards these benefits. At the same time, plans have reported that enrollee utilization of many of these benefits is low. To help ensure MA enrollees are fully aware of all available supplemental benefits and to promote equitable access to care, we will now require MA plans to notify enrollees mid-year of the unused supplemental benefits available to them. The notice will list any supplemental benefits not utilized by the enrollee during the first 6 months of the year (January 1 to June 30). Currently, MA plans are not required to send any communication specific to an enrollee's usage of supplemental benefits and CMS believes such a notice could be an important part of a plan's overall care coordination efforts. As finalized, this policy will educate enrollees on their access to supplemental benefits to encourage greater utilization of these benefits and ensure MA plans are better stewards of the rebate dollars directed towards these benefits.

g. Annual Health Equity Analysis of Utilization Management Policies and Procedures

We are finalizing regulatory changes to the composition and responsibilities of the Utilization Management (UM) committee. These policies will require that at least one member of the UM committee have expertise in health equity. These policies will also require that the UM committee conduct an annual health equity analysis of the use of prior authorization at the plan-level. The analysis will examine the impact of prior authorization on enrollees with one or more of the following social risk factors (SRFs): (i) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (ii) having a disability. To enable a more comprehensive understanding of the impact of prior authorization practices on enrollees with the specified SRFs at the plan level, the analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Finally, the policies will require MA organizations to make the results of the analysis publicly available on their plan's website in a manner that is easily accessible and without barriers.

h. Amendments to Part C and Part D Reporting Requirements

In this final rule, we are affirming our authority to collect detailed information from MA organizations and Part D plan

sponsors under current regulations, in keeping with the Biden-Harris administration's focus on improving transparency and data in MA and Part D. We are revising §§ 422.516(a)(2) and 423.514(a)(2) as proposed (with a minor clarification in § 422.516(a)) to be consistent with the broad scope of the reporting requirements. This will lay the groundwork for new program-wide data collections to be established through the Paperwork Reduction Act (PRA) process, which will provide advance notice to interested parties and be subject to public comment. An example of increased data collection could be service level data for all initial coverage decisions and plan level appeals, such as decision rationales for items, services, or diagnosis codes to have better line of sight on utilization management and prior authorization practices, among many other issues.

i. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services

Beneficiaries enrolled in Traditional Medicare and MA plans have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. Currently, Quality Improvement Organizations (QIO) act as the IRE and conduct these reviews. Under current regulations, MA enrollees do not have the same access to QIO review of a fast-track appeal as Traditional Medicare beneficiaries in connection with terminations of these types of services. In this final rule, we are finalizing proposals to: (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate the current provision that requires the forfeiture of an enrollee's right to appeal a termination of services to the QIO when the enrollee leaves the CORF or SNF or ends HHA services. These will bring MA regulations in line with the parallel reviews available to beneficiaries in Traditional Medicare and expand the rights of MA beneficiaries to access the fast-track appeals process in connection with terminations of HHA, CORF, or SNF services.

j. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products

Current regulations permit Part D sponsors to immediately remove from their formularies 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 proposed in the proposed rule titled ''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,'' which appeared in the December 27, 2022 **Federal Register** (hereinafter referred to as the December 2022 proposed rule), to permit Part D sponsors also 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.

Our proposed regulatory text in the December 2022 proposed rule did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products. Under current policy, Part D sponsors have to obtain explicit approval from CMS prior to making a midyear formulary change that removes a reference product and replaces it with a biosimilar biological product other than an interchangeable biological product. Further, if such a change is approved, the Part D sponsor may apply the change only to enrollees who begin therapy after the effective date of the change. In other words, enrollees currently taking the reference product are able to remain on the reference product until the end of the plan year without having to obtain an exception. In response to comments received on our initial proposal in the December 2022 proposed rule (discussed in section III.P. of this final rule), and to increase access to biosimilar biological products consistent with the Biden-Harris Administration's commitment to competition as outlined in Executive Order (E.O.) 14036: ''Promoting Competition in the American Economy,'' we proposed in the proposed rule titled ''Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' which appeared in the November 16, 2023 **Federal Register** (hereinafter referred to as the November 2023 proposed rule) to add substitutions of biosimilar biological products other than interchangeable biological products to the type of formulary changes that apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice.

Having now considered comments (discussed in section III.P. of this final rule) received on the proposals in both the December 2022 and November 2023 proposed rules, we are finalizing regulations to permit Part D sponsors that meet all requirements: (1) to immediately substitute an interchangeable biological product for its reference product, a new unbranded biological product for its corresponding brand name biological product, and a new authorized generic for its brand name equivalent; and (2) to substitute upon 30 days' notice any biosimilar biological product for its reference product.

k. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization

We are finalizing, with some modifications, interconnected proposals to: (a) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP, (b) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis, (c) limit enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (d) limit the number of D–SNP plan benefit packages an MA organization can offer for full-benefit dually eligible individuals in the same service area that it, its parent organization, or any entity that shares a parent organization with the MA organization offers an affiliated Medicaid MCO. This final rule will increase the percentage of full-benefit dually eligible MA enrollees who are in plans that—directly by the MA

organization or indirectly through the parent organization or a related entity—are also contracted to cover Medicaid benefits, thereby expanding access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. It will also reduce the number of MA plans overall that can enroll dually eligible individuals outside the annual coordinated election period, thereby reducing the number of plans deploying aggressive marketing tactics toward dually eligible individuals throughout the year.

l. For D–SNP PPOs, Limit Out-of-Network Cost Sharing

We are finalizing a limitation on out-of-network cost sharing for D–SNP preferred provider organizations (PPOs) for specific services. The final rule will reduce cost shifting to Medicaid, increase payments to safety net providers, expand dually eligible enrollees' access to providers, and protect dually eligible enrollees from unaffordable costs.

m. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes

Under existing regulations, CMS does not contract with and will not renew the contract of a D–SNP look-alike—that is, an MA plan that is not a SNP but in which dually eligible enrollees account for 80 percent or more of total enrollment. We are finalizing a reduction to the D–SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. This provision will help address the continued proliferation of MA plans that are serving high percentages of dually eligible individuals without meeting the requirements to be a D–SNP.

n. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation Appeals Process

We are finalizing regulatory language to address gaps and operational constraints included in existing RADV appeal regulations. Currently, if MA organizations appeal both medical record review determinations and payment error calculations resulting from RADV audits, both issues must be appealed and move through the appeals process concurrently, which we foresee could result in inconsistent appeal adjudications at different levels of appeal that impact recalculations of the payment error. This has the potential to cause burden, confuse MA organizations, and negatively impact the operations and efficiency of CMS's appeals processes. This final rule will standardize and simplify the RADV appeals process for CMS and MA organizations, as well as address operational concerns at all three levels of appeal. We are finalizing requirements that MA organizations must exhaust all three levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. This will ensure adjudication of medical record review determinations are final before a recalculation of the payment error is completed and subject to appeal. We are also finalizing several other revisions to our regulatory appeals process to conform these changes to our procedures.

Finally, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

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3. Summary of Costs and Benefits

TABLE A1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision	Description	Financial Impact
1. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria	We are finalizing changes to the MTM eligibility requirements to (1) codify the 9 core chronic diseases currently identified in sub-regulatory guidance and adding HIV/AIDS for a total of 10 core chronic diseases; (2) require Part D sponsors to include all core chronic diseases in their MTM targeting criteria, and to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking; and (3) revise the methodology for the MTM cost threshold to calculate the dollar amount based on the average annual cost of 8 generic drugs.	The revisions to the MTM targeting criteria being finalized in this rule have an estimated annual administrative cost of $192.7 million. We are unable to score this provision largely due to challenges with estimating Part A/B savings.
2. Improving Access to Behavioral Health Care Providers	We are finalizing changes to add a new facility-specialty type called "Outpatient Behavioral Health" to the network adequacy standards under § 422.116(b)(2). For purposes of the network adequacy requirements, the new facility-specialty type will be evaluated using time and distance and minimum number standards adopted in this rule. The new facility type will include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities. Based on comments from stakeholders we are also finalizing how an organization will determine when certain providers (NP, PA, CNS) may be utilized to meet network adequacy.	The new provision adds requirements for a new facility specialty type, which include providers some of which we have data for and some which are new and for which we lack data. Therefore, we cannot quantify the effects of this provision though we expect it may increase access which may qualitatively increase utilization.
3. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)	We are codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Further, we are codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure.	We do not expect any cost impact to the Medicare Trust Fund.
4. Enhance Guardrails for Agent/Broker Compensation	We are modifying agent/broker compensation requirements to further ensure payment arrangements and structure are aligned with CMS's statutory obligation to set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll prospective enrollees in plans that best fit their needs.	This provision has no costs because we are transferring funds the MA plans are already paying Marketing Agencies directly to the agents and brokers with some reductions due to some funds possibly being used inconsistent with the requirements of the regulation.

Provision	Description	Financial Impact
5. Special Supplemental Benefits for the Chronically Ill (SSBCI)	We are finalizing changes to require MA organizations to establish bibliographies for each SSBCI they include in their bid to demonstrate that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. This will shift the burden from CMS to the MA organizations to demonstrate compliance with this standard and help ensure that SSBCI items and services are offered based on current, reliable evidence. In addition, we are finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility and coverage criteria. We are modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
6. Mid-Year Enrollee Notification of Available Supplemental Benefits	We are finalizing requirements for MA plans to issue notices to enrollees who, by June 30th of a given year, have not utilized supplemental benefits, to ensure enrollees are aware of the availability of such benefits and ensure appropriate utilization.	Although these changes may result in increased utilization and ultimately create a savings to the Medicare Trust Fund, we cannot currently quantify this provision because it is new, and we lack data. See the Regulatory Impact Analysis for further discussion. The provision has an administrative cost of $23.7 million.
7. Annual Health Equity Analysis of Utilization Management Policies and Procedures	We are finalizing changes to the composition and responsibilities for the Utilization Management committee, to require: a member of the UM committee have expertise in health equity; the UM committee conduct an annual health equity analysis of prior authorization used by the MA organization using specified metrics; and require MA organizations to make the results of the analysis publicly available on its website.	We do not expect any cost impact to the Medicare Trust Fund.
8. Amendments to Part C and Part D Reporting Requirements	We are affirming our authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements and finalizing the proposed regulatory revisions to be consistent with the broad scope of the reporting requirements.	We do not expect any cost impact to the Medicare Trust Fund.
9. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	We are finalizing regulations to (1) require QIOs to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF and (2) eliminate the provision requiring the forfeiture of an enrollee's right to appeal to the QIO a termination of services decision when they leave the facility.	The revisions to this provision have an estimated annual administrative cost of $683,910. This is a transfer from MA plans to QIOs; MA plans have a reduced cost while QIOs have a corresponding increased cost.

Provision	Description	Financial Impact
10. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products	We are finalizing regulations to permit Part D sponsors to immediately substitute authorized generics for corresponding brand name drug products, interchangeable biological products for their reference products, and unbranded biological products marketed for the brand name biological product marketed under the same biologics license application. We also are finalizing regulations to permit substitutions of all biosimilar biological products with 30 days advance notice.	We do not expect any cost impact to the Medicare Trust Fund.
11. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	We are finalizing, with some modifications, policies to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP for full-benefit dually eligible individuals, (c) limit enrollment in certain D-SNPs to those full-benefit dually eligible individuals who are also enrolled in an affiliated Medicaid MCO, and (d) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.	Over a 10-year horizon, we estimate a $1.3 billion savings to the Trust Fund for Part D plans and an additional $1 billion savings to the Trust Fund for Part C plans.
12. For D-SNP PPOs, Limit Out-of-Network Cost Sharing	We are finalizing a limitation on D-SNP PPOs' out-of-network cost sharing for certain Part A and Part B benefits, on an individual service level.	We do not expect any cost impact to the Medicare Trust Fund.
13. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes	We are lowering the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.	We estimate this provision will have an average annual impact of less than $1M for plan years 2025-2027 due to non-SNP MA plans meeting the lower D-SNP look-alike threshold transitioning enrollees into other plans. We also estimate this provision will have an average annual impact of less than $1M on MA plan enrollees for plan years 2025-2027 due to enrollees choosing a different plan. We expect cumulative annual costs to non-SNP MA plans and MA plan enrollees beyond plan year 2027 to also be less than $1M per year.

Provision	Description	Financial Impact
14. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process	We are revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated because RADV payment error calculations are based upon the outcomes of medical record review determinations. We are also finalizing other revisions to our appeals process to conform with these proposed changes. The changes could reduce burden on some MA organizations that, absent these revisions, will have otherwise potentially submitted payment error calculation appeals that could have been rendered moot by certain types of medical record appeals decisions. The potential reduction in burden to MA organizations cannot be quantified prior to the implementation of the new appeals process and until appeals have been fully adjudicated. While the MA RADV appeals regulations have been in place for a period of years, CMS did not issue RADV overpayment findings to MA organizations as we worked to finalize a regulation on our long-term RADV methodology. Therefore, any impact of these policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.	The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes.

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B. Background and Summary of the Final Rule

In this final rule, CMS addresses many of the remaining proposals from the December 2022 proposed rule in addition to the proposals from the November 2023 proposed rule. There are several proposals from the December 2022 proposed rule that were not finalized. CMS may address these proposals in a future final rule.

We received 3,463 timely pieces of correspondence containing one or more comments on the November 2023 proposed rule. Some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

C. General Comments on the December 2022 Proposed Rule and the November 2023 Proposed Rule Proposed Rule

We received some overarching comments related to the December 2022 and the November 2023 proposed rules, which we summarize in the following paragraphs:

Comment: A commenter expressed concern that CMS had not provided sufficient time for plan sponsors to understand the impact of recently finalized regulations, and the changes they have implemented, before proposing more policies that build on these areas. They recommended that in future years CMS allows time to measure and observe the impact of policy changes on plan sponsors and their members prior to layering new proposals.

Response: We appreciate the commenter's concern regarding the plans having enough time to understand the impact of finalized regulations. We will take their recommendation into consideration for future rulemaking.

Comment: A commenter requested that CMS extend the comment period by 60 days, through March 5, 2024, so they could effectively use the extended period in planning and preparing a response.

Response: Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of **Federal Register**) on November 3, 2023. We did not extend the comment period because we believe the required 60 days provided the public with adequate time to prepare and submit responses.

Comment: In response to CMS–4201–P, a commenter suggested that CMS had not allowed for a 60-day comment period for the proposed rule because the beginning of the comment period was calculated from the date the proposed rule was made available for public inspection on the **Federal Register** website rather than the date that it appeared in an issue of the **Federal Register**. The commenter recommended that CMS provide an additional 60-day comment period on the proposed rule.

Response: Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of **Federal Register**) on December 14, 2022. We believe that beginning the comment period for the proposed rule on the date it became available for public inspection at the Office of the Federal Register fully complied with the statute and provided the required notice to the public and a meaningful opportunity for interested

parties to provide input on the provisions of the proposed rule.

D. Status of the Overpayment Proposal in the December 27, 2022, Proposed Rule

Under the governing statute, any Medicare Advantage Organization (MA organization) that ''has received an overpayment,'' 42 U.S.C. 1320a–7k(d)(1), must ''report and return the overpayment,'' 42 U.S.C. 1320a–7k(d)(1)(A), no later than ''60 days after the date on which the overpayment was identified'' 42 U.S.C. 1320a–7k(d)(2)(A). CMS implemented this statutory overpayment provision through a May 23, 2014, final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs''. See 79 FR 29844. A group of MA organizations challenged that rule's inclusion of instances where an MA organization ''should have determined through the exercise of reasonable diligence . . . that [it] has received an overpayment'' in the regulation's definition of ''identified,'' 42 CFR 422.326(c). The District Court for the District of Columbia held that this regulatory provision was impermissible under the statute. *See 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). CMS views the District Court's ruling as having invalidated the definition of ''identified'' set out in 42 CFR 422.326(c). However, MA organizations remain obligated to report and return all overpayments that they have identified within the meaning of the statute, 42 U.S.C. 1320a–7k(d)(2)(A). In the December 27, 2022 proposed rule titled ''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'' (the December 2022 proposed rule), CMS proposed revisions to regulations primarily governing Medicare Advantage (MA or Part C) and the Medicare Prescription Drug Benefit (Part D) (87 FR 79452). CMS proposed in the December 2022 proposed rule to remove the existing definition of ''identified'' in the Parts C and D overpayment regulations at 42 CFR 422.326 and 423.360 (as well as the corresponding Parts A and B regulation) (*see* 87 FR 79559). Under the Parts C and D overpayment proposal, an MA organization or Part D sponsor would have identified an overpayment when it had actual knowledge of the existence of the overpayment or acted in ''reckless disregard'' or ''deliberate ignorance'' of the overpayment. CMS has received inquiries regarding this proposal and want to be clear that it remains under consideration and that CMS intends to issue a final rule to revise the definition of ''identified'' in the overpayment rules as soon as is reasonably possible.

E. Information on Cyber Resiliency

In light of recent cybersecurity events impacting health care operations nationally, we expect all payers to review and implement HHS's voluntary *HPH Cyber Performance Goals* (CPGs). These CPGs are part of *HHS' broader cybersecurity strategy* and designed to help health care organizations strengthen cyber preparedness, improve cyber resiliency, and ultimately protect patient health information and safety. We welcome input on our approach via email at *hhscyber@hhs.gov.*

II. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Definition of Network-Based Plan (§§ 422.2 and 422.114)

Private-fee-for-service (PFFS) plans were established by the Balanced Budget Act of 1997 (Pub. L. 105–33) and were originally not required to have networks. The Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) revised the PFFS requirements to require that, beginning with contract year 2011, PFFS plans have a network when operating in the same service area as two or more network-based plans. 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)(iii)), 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 54249). A network-based plan, however, has meaning in contexts other than PFFS. To ensure that the definition is readily and more broadly accessible for those seeking requirements related to network-based plans, we proposed in the December 2022 proposed rule (87 FR 79569) to move the definition of a network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2. Further, we proposed that the PFFS provision at § 422.114(a)(3)(ii) will continue to include language specifying the network requirement.

This proposed change has no policy implications for other provisions in part 422 in which the definition or description of network plans plays a role, for example, the network adequacy provisions at § 422.116 and the plan contract crosswalk provisions at § 422.530. However, in specifying the network adequacy requirements for the various plan types, § 422.116(a)(1)(i) references the current definition of a network-based plan at § 422.2 even though the definition for network-based plan currently remains at § 422.114(a)(3)(ii) because CMS inadvertently finalized what was intended to be a conforming change to § 422.116(a)(1)(i) [1] before we finalized our proposal to move the definition of network-based plan to § 422.2. In this final rule, we are moving the definition to § 422.2, making the current cross reference at § 422.116(a)(1)(i) correct. With respect to the regulation at § 422.530(a)(5), that provision 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 and refers to network-based PFFS plans without citing a specific definition. Therefore, we do not believe any amendment to § 422.530 is necessary in connection with moving the definition of network-based plan to § 422.2.

We did not receive any public comments on our proposal to move the definition and are finalizing the proposal for the reasons outlined in the December 2022 proposed rule with slight modifications to reorganize the regulation text for additional clarity.

[1] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Program of All-Inclusive Care for the Elderly (88 FR 22120).

B. Past Performance

We established at §§ 422.502(b) and 423.503(b) that we may deny an application submitted by MA organizations and Part D sponsors that failed to comply with the requirements of a previous MA or Part D contract, which we refer to as ''past performance.'' We proposed several technical changes to the regulation text related to past performance. These changes are intended to clarify the basis for application denials due to past performance and to ensure that the factors adequately account for financial difficulties that should prevent an organization from receiving a new or expanded MA or Part D contract.

One factor we consider regarding the past performance of MA organizations and Part D sponsors is their record of imposition of intermediate sanctions, because intermediate sanctions represent significant non-compliance with MA or Part D contract requirements. To clarify the basis for application denials due to intermediate sanctions, at §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) we proposed to change ''Was subject to the imposition of an intermediate sanction'' to ''Was under an intermediate sanction.'' We proposed this revision because MA organizations and Part D sponsors may have a sanction imposed in one 12-month past performance review period and effective for all or part of the subsequent 12-month review period. For instance, CMS could impose a sanction in December 2022 that remains in effect until September 2023. The sanction would be in effect for the past performance review period that runs from March 2022 through February 2023 (for Contract Year 2024 MA and Part D applications filed in February 2023) and for the past performance review period that runs from March 2023 through February 2024 (for Contract Year MA and Part D applications filled in February 2024). Our proposal reflects our stated intent to deny applications from MA organizations and Part D sponsors when an active sanction existed during the relevant 12-month review period when we previously codified that intermediate sanctions are a basis for denial of an application from an MA organization or Part D sponsor in ''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) hereinafter referred to as the ''January 2021 final rule.'' When we codified this requirement, a commenter requested that sanctions lifted during the 12 months prior to the application denial be excluded from past performance. We responded that ''The applying organization will receive credit for resolving the non-compliance that warranted the sanction during the next past performance review period, when, presumably, the organization will not have an active sanction in place at any time during the applicable 12-month review period'' (86 FR 6000 through 6001). Since an intermediate sanction may be active during multiple consecutive review periods, our proposed language clarifies that an organization's application may be denied as long as the organization is under sanction, not just during the 12-month review period when the sanction was imposed.

An additional factor we consider regarding the past performance of MA organizations and Part D sponsors is involvement in bankruptcy proceedings. At §§422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C) we proposed to incorporate federal bankruptcy as a basis for application denials due to past performance and to conform the two paragraphs by changing the text to ''Filed for or is currently in federal or state bankruptcy proceedings'' from ''Filed for or is currently in State bankruptcy proceedings,'' at § 422.502(b)(1)(i)(C) and ''Filed for or is currently under state bankruptcy proceedings'' at § 423.503(b)(1)(i)(C). We codified state bankruptcy as a basis for an application denial for the past performance of an MA or Part D sponsor in ''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** on May 9, 2022 (87 FR 27704). We codified that requirement because bankruptcy may result in the closure of an organization's operations and entering into a new or expanded contract with such an organization is not in the best interest of the MA or Prescription Drug programs or the beneficiaries they serve. This concern is equally applicable to both federal and state bankruptcy, so we proposed to revise the regulation so that applications from MA organizations or Part D sponsors that have filed for or are in state or federal bankruptcy proceedings may be denied on the basis of past performance. In addition, we also proposed to correct two technical issues identified since the final rule was published in May 2022. At § 422.502(b)(1)(i)(B), we proposed to change the reference to the requirement to maintain fiscally sound operations from § 422.504(b)(14) to the correct reference at § 422.504(a)(14). We also proposed to remove the duplication of § 422.502(b)(1)(i)(*A*) and (*B*).

We invited public comment on this proposal and received several comments in support of this proposal. We received no comments opposing this proposal. Therefore, we are finalizing this proposal without modification.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. 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 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 regulations at §§ 422.550 and 423.551, respectively. These regulations require 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'' [2] 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's requirements. If a change of ownership occurs and a novation agreement is not completed and the entities fail to provide advance notification to CMS, the current 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

[2] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c12.pdf.*

the new owner through the novation agreement 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 regulations do not fully address what happens when the contract becomes ''invalid'' due to a change of ownership without a novation agreement and/or advance notice to CMS, or in other words, what happens to the existing CMS contract that was held by the purchased entity. In that circumstance, CMS would still recognize the original entity as the owner, even if the contract is now held by a different entity. Therefore, we proposed to revise §§ 422.550(d) and 423.551(e) to make it clear that in such a circumstance, CMS may unilaterally terminate the affected contract in accordance with §§ 422.510(a)(4)(ix) and 423.509(a)(4)(ix), which establish that failure to comply with the regulatory requirements contained in part 422 or part 423 (if applicable) is a basis for CMS to unilaterally terminate an MA or Part D contract.

In addition, we are strengthening CMS's enforcement authority regarding this process through the proposed amendments to §§ 422.550(d) and 423.551(e). Pursuant to CMS's authority under sections 1857 and 1860 of the Act, we proposed to amend the regulations at §§ 422.550(d) and 423.551(e) to outline the enforcement process CMS will follow, which includes 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 either the novation agreement or the application process, must ensure that MA organizations and Part D Sponsors—through their respective legal entities—are eligible to contract with CMS. If CMS has no chance to assess the qualifications of the new entity and a change in ownership from one legal entity to another occurs without CMS approval of a novation agreement, CMS's ability to ensure the integrity of the MA and Part D programs and ability to monitor a contract's activity under the new legal entity would be compromised, thereby putting enrollees at risk. Thus, any change in ownership from one legal entity to another requires CMS to determine whether the new entity meets the statutory and regulatory requirements for operating a contract under the MA or Part D programs.

We proposed to impose 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. Such sanctions will remain in place until CMS approves the change of ownership, (including execution of an approved novation agreement) or the contract is terminated. We also proposed to provide an opportunity for organizations to demonstrate that the legal entity assuming ownership by way of a change of ownership without a novation agreement meets the requirements set forth by our regulations. 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 MA or Part D 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 an MA or Part D contract in the same service area and fails to apply for an MA or Part D contract in the same service area at the next opportunity to apply, 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 termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x).

Imposition of intermediate sanctions under §§ 422.750(a)(1) and (a)(3) and 423.750(a)(1) and (a)(3) triggers the past performance rules applicable under §§ 422.502(b)(1) or 423.503(b)(1). Imposition of intermediate sanctions is a factor considered under CMS's evaluation and determination of an organization's information from a current or prior contract during the MA and Part D application process.

We solicited comments on these proposals. We appreciate stakeholders' input on the proposed changes. We received the following comments and have provided responses.

Comment: A commenter suggested that CMS not terminate a contract when a change of ownership has occurred without notification to CMS, but rather suggested CMS apply a substantial penalty or fine to the new legal entity.

Response: In the interest of managing the MA and Part D programs and protecting all enrollees, CMS must ensure, through the application process, that MA organizations and Part D sponsors are eligible to contract with CMS. This is existing policy that is also consistent with statutory requirements under sections 1855 and 1857 and 1860D–12 of the Act. The option to terminate the contract is a critical tool for CMS to ensure that only qualified entities can contract with CMS to serve enrollees. Imposing a substantial penalty or fine on the new owner would not protect enrollees who are already in MA or Part D plans that cannot adequately serve them. Moreover, under §§ 422.550(d)(2) and 423.551(e)(2), entities can cure any deficiencies within 30 days of the imposition of intermediate sanctions. If an entity wishes to avoid termination, it will have the opportunity to do so.

Comment: A commenter indicated that the proposed approach should not apply to those changes of ownership that occur under the same parent organization.

Response: In order to ensure the integrity of the MA and Part D programs, CMS must review any change in ownership from one legal entity to another, regardless of the relationship to the parent organization, to confirm whether the new legal entity meets the regulatory requirements for operating a contract in a given service area. As previously indicated, 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,'' [3] 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's requirements.

Comment: A commenter expressed concern that CMS's application timelines would negatively impact potential changes of ownership and suggested instead that CMS not impose the proposed sanctions or that CMS implement the sanctions for a period of

[3] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c12.pdf.*

time that is less time than the application cycle.

Response: As previously noted, CMS must determine whether the new legal entity involved in the change in ownership meets all CMS requirements for operating a MA contract. CMS must also have the opportunity to review and evaluate the new entity. When a change in ownership from one legal entity to another occurs without CMS approval, it compromises CMS's ability to ensure the integrity of the MA and Part D programs and hampers CMS's ability to monitor a contract's activity under the new legal entity, thereby putting enrollees at risk. The ability of CMS to ensure that MA and Part D plans are adequate to cover enrollees' health care needs outweighs concerns about potential timeline issues.

We believe that our process provides a sufficient opportunity for organizations to demonstrate, and CMS to determine, that they meet all CMS's requirements as set forth in our regulations.

Comment: A commenter asked CMS to clarify the types of sanctions that would be applicable when a change of ownership without novation agreement occurs.

Response: CMS would impose enrollment and marketing sanctions, which are outlined in our regulations at § 422.750(a)(1) and (a)(3) and § 423.750(a)(1) and (a)(3). These sanctions will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement) or the contract is terminated.

After considering the comments received and for the reasons discussed in the proposed rule and our responses to comments, we are finalizing our proposal to amend the regulations at §§ 422.550(d) and 423.551(e) with technical corrections to the cross-references proposed in § 423.551(e). The cross-references in paragraphs (e)(1) and (e)(2) have been corrected to reflect the appropriate Part D sections in the final regulatory text in this final rule. In addition, we are finalizing minor grammatical and organizational revisions to the regulations to improve the readability and clarity of the text.

B. Part D Global and Targeted Reopenings (§§ 423.308 and 423.346)

1. Executive Summary

2. Provisions of the Proposed Regulation (Preamble)

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 that pertain to the information 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 payment determinations. Therefore, we established that CMS may rectify any final payment determination issues in a reopening provision at § 423.346. In the January 2005 Part D final rule, we established that a reopening was at CMS' discretion and could occur within the following timeframes after the final payment determination was issued: (1) 12 months for any reason, (2) 4 years for good cause, or (3) 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 our December 2022 proposed rule, we proposed to codify the definitions of ''global reopening'' and ''targeted reopening.'' We also proposed to modify the timeframe CMS may perform 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 proposed to codify the circumstances under which CMS will notify the sponsor(s) of our intention to perform a final payment determination reopening and the requirement for CMS to announce when it has completed a reopening. We are finalizing our proposed changes without modifications.

a. 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 revisions of prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) data due to plan corrections, CMS system error corrections, post reconciliation claims activity, and audit and other post reconciliation oversight activity. Based on our experience in the Part D program and the PDE and DIR data changes, we understood that this process would require CMS to perform an initial payment determination reopening every contract year.

By calendar year 2013, CMS had reopened the 2006, 2007, and 2008 Part D payment reconciliations and, approximately 4 years after those reopenings were completed, began subsequent Part D payment reconciliation reopenings (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 these reopening provisions), 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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/part%20dreopeningannoucement_199.pdf*).

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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/second%20reopening%20of%20the%202011%20part%20d%20reconciliation_final_403.pdf*) and HPMS memorandum, ''Reopening of the 2014 Final Part D Reconciliation for Employer Group Waiver Plans (EGWPs),'' January 11, 2017 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cy14%20egwp%20reopening%20announcement_01-11-17_404.pdf*). 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 of the reopening timeframes described in the current regulation at § 423.346(a)(1) through (3).

Although CMS has in recent experience utilized targeted reopenings as part of our process to correct certain issues, 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 4 years after the Part D payment reconciliation for that year.

b. 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 4 years of announcing the completion of that reconciliation, CMS performs 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 the 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 the prior example, 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, as discussed subsequently in this section.

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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms%2520memo_reopen%2520and%2520overpay_04-06-2018_205.pdf*). 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 proposed 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 an establishment of good cause for reopening. This 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 of the look-back period, we would perform the global reopening for that contract year within the new 6-year timeframe, to recoup the PDE and DIR related overpayments reported by sponsors for that contract year (and process underpayments).

Prior to the new reopening timeframe going into effect, CMS will provide operational guidance, as has been done for past regularly scheduled global reopenings. The following example describes the timing for performing the scheduled global reopening. The data for the 2020 Part D payment reconciliation was due in June 2021. That reconciliation was completed in November 2021. Assuming a 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 in 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 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.

Comment: We received a comment that supported our proposal and our efforts to align the look-back period with the reopening timeframe.

Response: We thank the commenter for the support.

Comment: A commenter stated that while they do not have a conceptual problem with expanding the timeframe for overpayments associated with PDE record data and DIR data, they were concerned that looking back more than 4 years would result in administrative costs that exceed the value of the overpayment recoupment and recommended that CMS withdraw the proposal unless an analysis demonstrates that the expanded timeframe would result in overpayment

recoupments that exceed increased administrative costs.

Response: We are not, as the commenter states, expanding the timeframe for overpayments. Under the existing requirements, described at § 423.360(f), sponsors are required to report and return any overpayment identified within the 6 most recently completed payment years. To clarify, we proposed to modify the reopening timeframe, described at § 423.346(a)(2), which does not have any impact on the existing timeframe for reporting and returning overpayments.

We decline the commenter's recommendation to withdraw the proposal unless an analysis demonstrates that the expanded timeframe would result in overpayment recoupments that exceed increased administrative costs. We do not believe that expanding the reopening timeframe from within 4 years to within 6 years will result in any additional burden. Additionally, the intent of the proposed change is not strictly focused on overpayment recoupment, but rather, is a remedy to operational challenges associated with the misalignment of the overpayment look-back period and the reopening timeframe.

Comment: A commenter expressed concerns that DIR fees collected from pharmacies challenge patient access and pharmacies' viability. The commenter was concerned that extending the timeframe at § 423.346(a)(2) from within 4 years to within 6 years without any guardrails or protections in place for community pharmacies could lead to instances in which sponsors take advantage of the process to further claw back payments from pharmacies. To address this concern, the commenter requested that CMS consider establishing protections to prevent sponsors from recouping pharmacy overpayments.

Response: The intent of the proposed change is to remedy operational challenges associated with the misalignment of the reopening timeframe, described at § 423.346(a)(2), and 6-year overpayment look-back period, described at § 423.360(f). The change in the reopening timeframe from within 4 years to within 6 years does not, in any way, change a sponsor's responsibility to report and return overpayments within the 6-year look-back period. The impact of DIR fees collected from pharmacies, pharmacy claw backs, and the recoupment of overpayments from pharmacies are outside of the scope of the proposed change.

After consideration of comments, we are finalizing the proposed requirements related to aligning the timing of reopenings to the overpayment look-back period without modification.

c. Standards for Performing Global and Targeted Reopenings

Consistent with the existing regulation at § 423.346(a) and (d), reopenings are at CMS's 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 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 completed after the deadline to submit data for the scheduled global reopening. In addition, we are unlikely to conduct a reopening solely pursuant to a sponsor's request.

We proposed 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. We also proposed that if CMS has sent a nonrenewed or terminated contract the ''Notice of final settlement,'' as described at § 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 § 423.521, 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 proposed to codify these inclusion criteria at § 423.346(g).

We also proposed 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 targeted Part D contract reopenings 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. Accordingly, sponsors would not be aware of this specific inclusion criteria unless CMS informed the sponsors of the CMS-identified issue and the sponsors' contracts were impacted. Therefore, we proposed that CMS notify sponsors of this specific inclusion criteria via the proposed reopening notification and/or the proposed reopening completion announcement.

We did not receive comments on this section of the proposal and are finalizing the proposed requirements related to the standards for performing global and targeted reopenings without modification.

c. Reopening Notification and Reopening Completion Announcement

We proposed to add new paragraphs (e) and (f) at § 423.346 to codify our existing policy regarding reopening notifications and reopening completion announcements, respectively. We proposed 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 proposed to notify the sponsor(s) only after CMS completes 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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/second%20reopening%20of%20the%202011%20part%20d%20reconciliation_final_403.pdf*).

We proposed at § 423.346(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 proposed that the deadline to submit this data will be at least 90 calendar days after the date of the notice.

In addition, we proposed 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 proposed 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 proposed 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 § 423.346(f)(2), we proposed to include in the announcement 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 proposed to specify which contracts or contract types are included in the reopening in both the announcement of the completion of the reopening and the reopening notification because CMS' proposal would not require issuing 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 § 423.346(f)(3), we proposed 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 proposed to include the date by which a sponsor must submit an appeal, pursuant to § 423.350, if the sponsor disagrees with the reopening results.

We did not receive comments on this section of the proposal and are finalizing the proposed requirements related to the reopening notification and the announcement of the completion of the reopening without modification.

d. Definitions of ''Global Reopening'' and ''Targeted Reopening''

We proposed to establish definitions of global reopening and targeted reopening at § 423.308. We proposed to define a global reopening as a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria described at proposed § 423.346(g). We proposed to define a targeted reopening as a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that the meet the inclusion criteria described at proposed § 423.346(g). Finally, consistent with these proposed definitions, we proposed to include the terms ''global reopening'' and ''targeted reopening'' at the beginning of existing § 423.346(a) to clarify that the reopenings that CMS may perform under § 423.346(a) may be global or targeted, as defined in proposed § 423.308.

Comment: We received a comment supporting our proposal to codify the definitions of ''global reopening'' and ''targeted reopening.''

Response: We thank the commenter for the support.

We are finalizing the proposed definitions of ''global reopening'' and ''targeted reopening'' without modification.

The proposals described in this section of the final rule are consistent with our current guidance and requirements. None of the proposed changes would place additional requirements on Part D sponsors, nor do the proposed changes to §§ 423.308 and 423.346 place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs). Our proposed rule does 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, as our changes do not result in additional burden, we have not included a discussion a of this provision in the COI section of this rule. In addition, we are not scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

Based on the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed changes to the reopening provision at § 423.346 and the related changes to § 423.308 without modification.

C. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Nonrenewing, or Otherwise Terminating a Contract (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

In our December 2022 proposed rule, we proposed 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, nonrenewed, or otherwise terminated. As described subsequently in this section, we are finalizing our proposed changes.

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. This final rule will 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 a 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 subsequently in this section. 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 one year to the next. 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 subsequently in this section. 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.[4]

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.[5] 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 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.[6]

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

[4] 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.

[5] 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.

[6] Once a contract has completed final settlement, the MA organization or Part D sponsor may still have financial responsibilities under any other applicable statute or regulation.

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.

In our proposed rule, we proposed to codify longstanding and existing guidance pertaining to procedures for the final settlement process described in the previous paragraphs. In addition, we proposed to add a new appeals process for MA organizations or Part D sponsors that disagree with the final settlement amount. MA organizations 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 will 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 will 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 will be necessary or required. Failure to request appeal within 15 calendar days of the date of issuance of the notice of final settlement will indicate acceptance of the final settlement amount. We 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's final settlement amount calculation, we proposed to add two additional levels of appeal: (1) an informal hearing conducted by the CMS Office of Hearings to review CMS's initial determination, following a request for appeal of the reconsideration of CMS's 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 will only be available to appeal CMS's final settlement amount calculation and will 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 will 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 will 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 will 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 will 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 will be considered.

CMS did not receive comments on this section of the proposal.

2. Process for Appealing 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 will have to specify the calculation with which they disagree and the reasons for their disagreement, as well as provide evidence supporting the assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect. MA organizations and Part D sponsors will not be able to submit 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 purpose of retroactively adjusting a prior reconciliation.

CMS will 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 will 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 will 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 will be able to request an informal hearing from a CMS hearing officer. The MA organization or Part D sponsor will 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 will be required to provide a copy of CMS's decision, the findings or issues with which it disagrees, and the reasons why it disagrees with CMS's decision. As the hearing officer's review will be limited to a review of the existing record, the MA organization or Part D sponsor will not be able to submit new evidence to support its assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect in addition to the evidence submitted during CMS's reconsideration.

The CMS hearing officer will provide written notice of the time and place of the informal hearing at least 30 days before the scheduled date and the CMS

reconsideration official will provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. The CMS hearing officer will not receive new testimony or accept new evidence in addition to the evidence submitted by the MA organization or Part D sponsor during CMS's reconsideration to support its assertion that CMS's calculation of the final settlement amount is incorrect.

Once the hearing officer has reviewed the record, the hearing officer will 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 will 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 will be able to request an additional, final review from the CMS Administrator. The MA organization or Part D sponsor will 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 will be able to submit written arguments to the Administrator for review but will not be able to submit evidence in addition to the evidence submitted during CMS's reconsideration.

The CMS Administrator will 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 will 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 will review the information included in the record of the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor. Based on this review, the Administrator may uphold, reverse, or modify the hearing officer's decision. The Administrator's decision will be final and binding and no other requests for review will 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 will 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 will be limited to CMS's calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. The MA organization or Part D sponsor will bear the burden of proof by providing evidence demonstrating that CMS's calculation of the final settlement amount is incorrect.

CMS did not receive comments on this section of the proposal.

3. Proposed Amendments to Regulations (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

a. Definitions

We proposed to amend §§ 422.500(b) and 423.501 to add several definitions relevant for the codification of the final settlement process.

First, we proposed to add a definition for the term *final settlement amount,* which will 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, nonrenewal, or other termination. The proposed definition provides that CMS will calculate the final settlement amount by summing retroactive payment adjustments for a contract that accumulate after that contract consolidates nonrenews, 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 proposed to add a definition for the term *final settlement process* as the process by which CMS will 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 previously in section XXX) 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* will specify that the final settlement process begins after all applicable reconciliations have been completed.

b. Final Settlement Process and Payment

We proposed 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 will be made.

CMS will calculate and 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 proposed to codify that CMS will 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 will 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.

At paragraph (b) of proposed §§ 422.528 and 423.521, we proposed to establish that MA organizations and Part D sponsors will have 15 calendar days from the date of issuance of the notice to request an appeal. We proposed 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 will be required, and that, if an MA organization or Part D sponsor does not request an appeal within 15 calendar days, CMS will not consider any subsequent requests for appeal of the final settlement amount.

At paragraph (c) of proposed §§ 422.528 and 423.521, we proposed to codify the actions that will take place if an MA organization or Part D sponsor does not appeal the final settlement amount. Specifically, at paragraph (c)(1), we proposed to specify that, if an MA organization or Part D sponsor owed a final settlement amount from CMS does not appeal, CMS will remit payment within 60 calendar days of the date of the issuance of the notice of final settlement. At proposed paragraph (c)(2), we proposed that an MA organization or Part D sponsor that owes money to CMS and does not appeal will 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 will be subject to having any debts owed to CMS referred to the Department of the Treasury for collection.[7]

At paragraph (d) of proposed §§ 422.529 (for MA) and 423.522 (for Part D), we proposed to establish the actions following submission of a request for an appeal that will be taken.

At paragraph (e) of proposed §§ 422.529 (for MA) and 423.522 (for Part D), we proposed 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 will no longer apply retroactive payment adjustments for the terminated contract and there will be no adjustments applied to the final settlement amount.

c. Requesting an Appeal of the Final Settlement Amount

We proposed 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 will 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 proposed to establish requirements that will apply to MA organizations' and Part D sponsors' requests for appeal of the final settlement amount calculation.

Specifically, at proposed paragraph (a)(1), we proposed to establish the process under which an MA organization or Part D sponsor may request reconsideration of the final settlement amount. We proposed to specify that the 15-calendar-day period for filing the request will begin on the date the notice of final settlement from CMS is issued. We also proposed that MA organizations and Part D sponsors will have to include in their request: (1) the calculation with which they disagree and (2) evidence supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further specify that CMS will not consider (for purposes of retroactively adjusting a prior reconciliation), and 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.

At proposed paragraph (a)(1)(iii), we proposed to establish that the CMS reconsideration official will review the final settlement calculation and evidence timely submitted by the MA organization or Part D sponsor supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further proposed to establish that the CMS reconsideration official will inform the MA organization or Part D sponsor of their decision on the reconsideration in writing and that their decision will be final and binding unless the MA organization or Part D sponsor requests a hearing officer review.

At proposed paragraph (a)(2), we proposed to establish that MA organizations and Part D sponsors that disagree with CMS's reconsideration decision under paragraph (a)(1) of this section will be able to request an informal hearing by a CMS hearing officer.

Specifically, at paragraph (a)(2)(i), we establish that MA organizations and Part D sponsors will 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 proposed that MA organizations and Part D sponsors will have to include in their request a copy of CMS's decision, the specific findings or issues with which they disagree, and the reasons for which they disagree. At paragraph (a)(2)(iii), we proposed to establish the informal hearing procedures. Specifically, we proposed that the CMS hearing officer will provide written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date and the CMS reconsideration official will provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. We further proposed that the hearing will be conducted by a hearing officer who will neither receive testimony nor accept new evidence. We finally proposed that the hearing officer will be limited to the review of the record that CMS had when making its decision. At paragraph (a)(2)(iv), we proposed that the CMS hearing officer will 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 proposed 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 proposed to establish at paragraph (a)(3) that MA organizations and Part D sponsors that disagree with the hearing officer's decision will be able to request a review by the CMS Administrator.

At paragraph (a)(3)(i), we establish that MA organizations and Part D sponsors will 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 proposed that the CMS Administrator will 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 proposed that if the Administrator declines to review the hearing officer's decision, the hearing officer's decision will be final and binding. We proposed at paragraph (a)(3)(iii) that, 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 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 proposed that the Administrator's determination will be final and binding.

At proposed paragraph (b), we proposed 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 proposed to establish that the Part D sponsor's appeal will be limited to CMS's calculation of the final settlement amount. We further proposed that CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. At proposed paragraph (b)(2), we proposed that the MA organization or Part D sponsor will bear the burden of proof by providing evidence demonstrating that

[7] 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.

CMS's calculation of the final settlement amount is incorrect.

At proposed paragraph (c), we proposed 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 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-calendar-day timeframe, CMS will 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 will limit an MA organization or Part D sponsor's responsibility to comply with any other applicable statute or regulation.

CMS did not receive comments on this section of the proposal.

Based on the lack of comments received, we are finalizing the additions to §§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522 to codify the final settlement process as proposed.

D. 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 [8] 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.[9]

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. *https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare.* Hereinafter referred to as the January 2019 final rule). In January 2019 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) [10] 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 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 determines it is necessary to impose the maximum CMP amount permitted under statute, or an amount that is 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 proposed to modify its rules pertaining to minimum penalty amounts.

Specifically, we proposed to remove §§ 422.760(b)(3)(i)(E) and 423.760(b)(3)(i)(E), respectively, which is the cost-of-living multiplier. We also proposed 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, we proposed to revise and add new provisions §§ 422.760(b)(3) and 423.760(b)(3), which explain 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 paragraph (b) 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

[8] 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 amounts 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).

[9] 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.*

[10] 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.

non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

Once 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 will also be incorporated in forthcoming revised CMP calculation methodology guidance.

Comment: A commenter suggested that removing the minimum penalty amount increase policy would lead to inconsistencies, and a lack of parity, in the CMP amounts we impose.

Response: We disagree with this comment. First, as discussed above and in the proposed rule, CMS has always had the statutory authority to impose up to the maximum CMP amount authorized under sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act. Second, CMS would continue to follow our existing CMP methodology, which allows for parity, fairness, and consistency in calculating CMP amounts. We would only impose up to the maximum CMP amount in instances where we determine non-compliance warrants a higher penalty to adequately address the non-compliance.

After consideration of the comments received, we are finalizing our changes to §§ 422.760(b)(3) and 423.760(b)(3) as proposed.

E. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

1. MTM Eligibility Criteria (§ 423.153(d)(2))

a. Background

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. 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) [11] in their Part D drug management program (DMP) for MTM. CMS has codified the MTM targeting criteria at § 423.153(d)(2).

As discussed in the December 2022 proposed rule (87 FR 79452), MTM eligibility rates have steadily declined over time to 8 percent in 2020. In conjunction with the decreasing eligibility rates, CMS has observed near-universal convergence among Part D sponsors to the most restrictive targeting criteria currently permitted under § 423.153(d)(2). When CMS finalized the current regulatory requirements for targeting criteria over 13 years ago, CMS elected to continue to give plan sponsors significant flexibility in establishing their MTM eligibility criteria. However, sponsors have used this flexibility to adopt increasingly restrictive criteria that we believe are limiting access to MTM for vulnerable, clinically high-risk beneficiaries.

We performed an extensive analysis to identify potential disparities in MTM program eligibility and access, as discussed in the December 2022 proposed rule, and we identified the high cost threshold and increasingly restrictive plan criteria (*e.g.,* targeting select core chronic diseases or specific drugs) as the main drivers of the eligibility gaps. The targeting criteria used by most plans now require three or more chronic diseases, require eight or more Part D drugs, and target a narrow and variable list of chronic diseases. And because of variation in plans' criteria for MTM enrollment, 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. Under the current MTM cost threshold methodology at § 423.153(d)(2)(i)(C), the annual cost threshold for 2024 is $5,330, which also significantly limits the number of beneficiaries who are eligible to be targeted for MTM enrollment. In the December 2022 proposed rule, CMS proposed changes to the MTM program eligibility criteria to address these concerns and help ensure beneficiaries with more complex drug regimens who would benefit most from MTM services are eligible.

The proposed changes included:

- Requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current nine core chronic diseases in regulation,[12] 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 eight to five drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
- Revising the methodology for calculating the cost threshold ($5,330 in 2024) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020).

CMS received many comments on these proposed changes, including the following general comments, and our responses follow.

Comment: Many commenters cited studies that demonstrated the value of MTM services and supported changes to the targeting criteria to optimize therapeutic outcomes, decrease adverse medication events, and avoid unnecessary costs. Commenters also acknowledged that studies show medication-related problems such as poor medication adherence and polypharmacy are widespread among individuals taking multiple prescription medications. These studies emphasized the value of MTM, including maintaining the wellbeing of Part D enrollees, resolving medication-related problems, improving health outcomes, empowering patients, and coordinating care. Some commenters cited a study that showed net cost savings (*i.e.,* a reduction in total annual health expenditures minus patient copayments, coinsurance, and deductible amounts) divided by the incremental cost of providing MTM services resulted in a return on investment of more than $12 in cost savings for each $1 spent on MTM. Commenters added that when patients better understand the goals of their medication therapy, medication adherence may increase, and hospital readmissions can be reduced. One commenter cited an analysis by a regional Medicare Advantage plan that found enrollees who received a comprehensive medication review (CMR) had an average savings of up to $4,000 in medical claims compared to members who did not receive a CMR. The commenter stated that the analysis also found that all enrollees who received a CMR had a 5 percent reduction in total cost of care compared to those who were eligible for but did not receive a CMR. Another commenter emphasized that access to pharmacists'

[11] Defined at § 423.100.

[12] 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 (*).

clinical skills and increased opportunities for patient-centric care through MTM could help offset shortages of physicians and nurses. Lastly, commenters pointed out that MTM fosters collaboration between clinicians, pharmacists, and patients who take multiple medications and/or have multiple chronic diseases.

Several commenters agreed that the proposed changes to the MTM eligibility criteria have the potential to significantly improve the effectiveness of the MTM program and achieve equity for underserved Medicare patients. One commenter noted studies highlighting that individuals with multiple comorbid chronic conditions tend to have the greatest disparities in accessing the care and treatments they need. The commenter also cited studies that noted that the current MTM eligibility criteria do not optimally target beneficiaries most at risk of underuse or poor adherence and that eligibility is limited to beneficiaries with high drug use and high spending, which systematically excludes beneficiaries who could benefit from these services. Another commenter suggested that rather than using MTM to improve outcomes and reduce health care costs for Part D enrollees with multiple chronic diseases, plan sponsors have instead used it as a cost control tool by focusing on enrollees who take high-cost drugs.

Response: We thank the commenters for their support of the proposed changes to the MTM eligibility criteria to better focus on beneficiaries with more complex drug regimens who would benefit most from MTM. We appreciate the citation of many studies reinforcing the value of MTM and the need for more equitable access. Almost all of the chronic diseases targeted for MTM identified at section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act and in the current CMS MTM guidance (See HPMS Memorandum Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023) are more prevalent among minorities and lower income populations. As a result, we anticipate that these changes will increase eligibility rates among those populations by promoting more equitable access to MTM services and closing eligibility gaps.

Comment: Many commenters opposed the proposed eligibility criteria changes partially or in whole, and several expressed significant concerns about the costs and resource burden associated with implementing such a large-scale expansion of the MTM program. Some of these commenters opined that the proposed changes would increase Part D premiums and cost sharing for all enrollees. One commenter estimated that the proposed changes would more than double MTM administrative costs. Some commenters stated that the proposed MTM expansion would be cost-prohibitive without any documented benefit to enrollees. Another commenter suggested finalizing the proposed changes would result in a loss of rebate dollars that would otherwise be used to improve affordability or provide supplemental benefits that support enrollee well-being. Several commenters referenced competing priorities between the proposed MTM expansion and implementation of the Inflation Reduction Act of 2022 (IRA). A few commenters emphasized that many of the same resources needed to support IRA implementation for 2024 and beyond would also be needed to implement changes to the MTM program, and finalizing the MTM changes as proposed would put successful implementation of both the IRA and the MTM expansion at risk.

Response: We acknowledge the concerns raised regarding the cost and burden of the proposed expansion of MTM. In light of these comments, we are finalizing the proposed changes with modifications that will result in a more moderate program size increase and less burden and lower costs than initially estimated in our December 2022 proposed rule. We provide more details about the specific modifications in the responses to comments later in this section of the preamble.

Comment: Several commenters who were opposed to the proposed changes raised concerns about a decline in MTM program quality that could result from a significant increase in program size, which would dilute plans' ability to target MTM interventions to those beneficiaries who would most benefit from them. Other commenters were concerned that MTM providers may ''water down'' their approach due to the increased volume resulting in lower-value programs that satisfy the MTM requirements but are much less likely to improve health outcomes due to shorter consultations or fewer interventions. Another commenter stated that the pool of MTM vendors has decreased while costs have increased due to the loss of competition, hindering the ability of plan sponsors to administer quality MTM programs.

Response: We understand the commenters' concerns about the impact on the quality of the MTM programs and services delivered due to a large increase in program size as proposed. CMS is finalizing the proposed changes with modifications that will ensure a smaller increase in program size and promote the administration of high-value MTM programs. Currently, due to the increasing cost threshold and variations in the targeting criteria adopted 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 (for example, with the same chronic diseases and taking the same Part D drugs) may or may not be eligible for MTM depending on the criteria their plan requires. The eligibility criteria changes we are finalizing in this rule aim to address the key drivers of the eligibility gaps, discussed in detail in the December 2022 proposed rule, while maintaining a reasonable program size and the ability of plans to administer effective MTM services.

MTM is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. To continue to provide quality MTM services to an expanded population and better manage resources, we remind sponsors that the delivery of MTM may be tailored to meet each enrollee's needs. For example, the length of the CMR consultation or number of follow-up interventions needed following targeted medication reviews (TMRs) may vary between MTM enrollees with more complex drug regimens and those who are stable on their medication regimens as long as the minimum level of MTM services is met as specified in § 423.153(d)(1)(vii). Sponsors may also leverage effective MTM programs to improve several measures in the Medicare Part D Star Ratings and display page such as medication adherence, polypharmacy, and gaps in therapy. Lastly, while we acknowledge commenters' concerns regarding the availability of MTM vendors, we note that Part D plan sponsors may use in-house resources, one or more external vendors, or a combination of both, to administer their MTM programs.

Comment: Some commenters stated that a large increase in the MTM enrollee population would require significant resources and that there would be limited time to hire and train additional staff, implement the necessary processes, and upgrade clinical and administrative infrastructures. Commenters estimated needing to double or triple their staffing to accommodate MTM enrollment increases of up to 60 percent in one year. A commenter stated that many plan sponsors that utilize local

community pharmacists to furnish MTM services would not be able to meet the higher demand in time, or that there would be pressure to use call centers, possibly employing customer service representatives without clinical training, which may lead to lower quality of care or member experience. Other commenters were concerned that rapid expansion of the MTM program size would exacerbate the existing pharmacist workforce shortage or would not be feasible given the expanded scope of pharmacy practice. One commenter also suggested that MTM vendors would drop smaller clients to service larger ones as a result of not being able to hire enough pharmacists to accommodate the increase in MTM enrollees.

Response: We are optimistic that the increase in demand for MTM services will incentivize plan sponsors to strengthen their hiring efforts. It is not clear what methodology the commenters used to estimate staffing needed to accommodate certain MTM program size increases. However, CMS plans to finalize our proposed changes to the MTM eligibility criteria with the modifications described later in this section of the preamble. CMS believes that this scaled back MTM expansion may alleviate a portion of the staffing concerns raised by commenters.

Comment: A few commenters, particularly commenters representing dual eligible special needs plans (D–SNPs), were concerned that due to the higher prevalence of chronic diseases in their enrollees, they will be disproportionately impacted by the changes in the MTM eligibility criteria and estimated that the majority of their plan enrollment would be eligible for the MTM program. They asserted that it would not be feasible to perform outreach or offer the MTM services to all their enrollees.

A few other commenters stated that when combined the proposed changes would result in MTM enrollment increases that exceeded the estimated program-wide size (23 percent of Part D enrollees) in the proposed rule (for example, increasing enrollment to 60 percent of their Medicare population, by five times, etc.), depending on the population or type of plan. Commenters asserted that such an increase in MTM enrollment would increase administrative costs, resulting in increased premiums, and could limit the offering of Part D plans.

Response: We acknowledge that some Part D contracts may have actual MTM enrollment rates above or below the average rate for the program as a whole because they have higher or lower enrollments of beneficiaries with the chronic diseases targeted for MTM under the changes to the MTM requirements we are finalizing in this rule. This is also true under the current MTM requirements, and there is no evidence that higher than average MTM enrollment has increased administrative costs and thus premiums to the point of limiting Part D plans' offerings, including MA–PDs that are D–SNPs. However, based in part on considerations about how the estimated program size under the proposals in the December 2022 proposed rule would impact MTM enrollment differently across contracts and increase the MTM enrollment volume to greater levels than some sponsors could feasibly handle, we are finalizing the proposed changes to the MTM eligibility criteria with modifications that we expect to decrease estimated program size relative to the proposed rule.

Comment: Some commenters expressed concerns that Part D MTM programs overlap with other programs such as disease management or care management (including post-discharge medication reconciliation; hypertension, diabetes, and dyslipidemia case management; and annual wellness visits) and may cause enrollee confusion, frustration, or complaints due to multiple outreach attempts, beneficiaries not answering calls from the plan sponsor, or beneficiaries requesting to be placed on the plan's do-not-call list. A commenter discussed that MTM-like interventions occur outside of the Part D MTM program and achieve improvements to health outcomes, and many MTM services, such as drug-drug interaction (DDI) analyses, could be automated (outside of CMRs) without beneficiary participation.

Response: We believe that Part D MTM programs complement efforts under other programs rather than overlap with them. MTM programs—which use a comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence for beneficiaries at increased risk of medication-related problems due to having multiple chronic diseases and taking multiple Part D drugs—are distinct from disease-specific disease management programs. We acknowledge that recommendations arising from MTM services may result in referrals to other specialized, disease-specific programs that may not be a part of the Part D MTM program. To reduce the risk of beneficiary confusion and frustration, plan sponsors should be mindful of the timing and frequency of enrollee outreach for MTM relative to complementary disease management programs.

In addition, we remind Part D sponsors that while a CMR must be an interactive consultation with the beneficiary and the pharmacist or other qualified provider, other aspects of MTM may be automated as described in CMS MTM guidance (See HPMS Memorandum Correction to Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023).[13] As described in this guidance, sponsors are required to perform TMRs for all beneficiaries enrolled in their MTM program with follow-up interventions when necessary. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary for the beneficiary and/or their prescriber. These assessments could be person-to-person or system generated.

Comment: Many commenters stated that the proposed eligibility criteria changes would result in a substantive update to the Part D Star Rating MTM Program CMR Completion Rate measure (MTM Star Rating Measure) due to the program size expansion and impacts to resources. Therefore, the commenters urged CMS to move the MTM Star Rating Measure to a display measure for at least 2 years to adjust to the new levels. A few commenters suggested specification changes to the MTM Star Rating Measure. Other commenters suggested that expanding the program size in such a short timeframe would incentivize plans to prioritize quantity over quality of care.

Response: Per §§ 422.164(d)(2) and 423.184(d)(2), substantively updated Star Ratings measures are moved to the display page for at least 2 years after the substantive update is adopted.[14] Refer to sections VII.B.2 and VII.D of this final rule, where we address the proposal to modify the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure and discuss the weight of newly modified measures, respectively. The MTM Program Completion Rate for CMR measure is being updated in this rule to align with the revised targeting criteria finalized at § 423.153(d); the updated

[13] *https://www.cms.gov/files/document/memo-contract-year-2022-medication-therapy-management-mtm-program-submission-v-083121.pdf.*

[14] Information for measures on the display page are available online at: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data*. Please download the zipped file ''2024 Display Measures'' for display measure scores, data and explanatory technical notes.

measure will move to the display page entirely for the 2025 and 2026 measurement years and will return as a new measure to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. We will share the additional suggestions for specification changes with the Pharmacy Quality Alliance (PQA), the measure steward.

Comment: A few commenters suggested that MTM program expansion could be limited to those beneficiaries who are newly eligible for the Part D MTM program or have recently added, removed, or changed drugs. One commenter also asserted that the newly eligible would see the greatest benefit from MTM services, resulting in improved health outcomes and reduced overall costs. This commenter also stated that the value of the CMR declines for enrollees with no changes in health status and that broadening the targeted disease states would increase burden and administrative costs with diminishing benefits for both plan sponsors and enrollees. Another commenter suggested that enrollees who have had a CMR in the last 12 months should requalify for MTM only with the addition of a new drug to their drug regimen and/or a new disease state.

Response: 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. Furthermore, 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. These requirements are codified in the regulations at § 423.153(d)(1) and (2).

We acknowledge that the needs and goals of newly eligible MTM enrollees may be different from those who have already received MTM services and continue to be eligible for MTM. However, for both populations of beneficiaries, annual CMRs may be an opportunity to understand new information about the beneficiary, including but not limited to if the beneficiary's goals have changed, if they have new or unresolved medication therapy problems, or if they have any social risk factors that may be affecting their medication use that can only be assessed through an interactive consultation.

Comment: A few commenters suggested that CMS should engage the industry to determine alternative options for better targeting or increased CMR participation rather than finalize the proposed modifications to the eligibility criteria. A commenter stated that many MTM enrollees choose not to participate, and to be more consistent with the Administration's health equity goals, CMS should engage those already eligible, who have the greatest need. Another commenter suggested changes to the Medicare Plan Finder (MPF) that would highlight the value added by specific plans' MTM programs and provide guidance to beneficiaries on why selecting plans based on MTM program specifics may be beneficial. The commenter cited recent precedent in 2019 to 2020 when CMS engaged plans, PBMs, developers, and patient groups on how to improve the MPF, resulting in major improvements supported by a wide range of interested parties. A few commenters also suggested that CMS could engage plans and PBMs to assess MTM and alternative programs to determine whether MTM eligibility criteria expansion is warranted, whether to include cancer as a core chronic condition, the effect of including any additional core chronic diseases on specialized MTM provider training and program size, and whether MTM services are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens).

Response: Through this rulemaking, we have engaged numerous interested parties to solicit feedback on implementing MTM eligibility criteria changes. We have also engaged in our own analysis. As discussed in the December 2022 proposed rule, we conducted an extensive data analysis that identified several issues with the current MTM targeting criteria, and we proposed specific regulatory changes 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, we believed that 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.

As discussed later in this preamble, we are finalizing the proposals with modifications in response to public comments we received. However, we are committed to addressing the main drivers of the inequities in MTM program eligibility discussed in the December 2022 proposed rule. Accordingly, we will continue to request input from interested parties on improving aspects of the MTM program in the future, including enhanced targeting and better engagement with MTM enrollees. We will also look for opportunities to improve the information available for beneficiaries on CMS' websites about Part D MTM programs.

Comment: A few commenters suggested that additional analyses are needed to assess the effectiveness of MTM programs, optimize current MTM programs, and review alternative medication management methods already being used by plan sponsors and their contracted providers. One commenter asserted that CMS would be unable to determine which part of the eligibility criteria expansion worked or failed as they believed the metrics for MTM success to be ill-defined. The commenter also asked if CMS has conducted any evaluation of the requirement to target DMP enrollees for MTM enrollment. Another commenter encouraged CMS to find a new approach to measuring MTM success in the future through metrics that assess the quality of MTM services provided and not just the overall volume of services provided. Another commenter noted the documented successes of MTM in a number of situations but recognized room for improvement in the program. The commenter stated that in many cases, MTM benefits patients directly and can decrease the burden of healthcare costs, but that results are not consistent across the board, suggesting a need to increase the overall quality of MTM evaluations. The commenter concurred with researchers in recommending that future studies should consider increasing study size and incorporating multiple sites to bolster the reliability of the results and suggested that CMS could use its authority to influence changes to MTM studies. Another commenter suggested that further study can help improve the MTM program due to limited evidence that MTM improves medication adherence and patient outcomes. The commenter recommended that CMS initiate a study including a large set of geographically diverse, Part D plans to better understand the overall effectiveness of the MTM program and

potential areas for improvement. The commenter also suggested that it would be particularly useful to understand the experience and impact of pharmacists' involvement in MTM programs.

Response: We routinely analyze CMS and plan-reported data to oversee the Part D MTM programs, including implementation of the new requirement to target DMP ARBs for MTM enrollment. However, we agree that additional analysis would be beneficial to assess MTM program effectiveness, and we will continue to explore ways of conducting such analysis. We appreciate the comments on potential research and analysis topics and agree that the high degree of variability between MTM program targeting criteria has made it difficult to evaluate MTM programs. We are hopeful that standardizing the criteria as finalized in this rule will allow more research to be done on MTM outcomes. We will also engage with industry to develop additional consensus-based measures to evaluate the quality of MTM programs which may be considered for the Star Ratings program in the future, and we are encouraged by recent efforts by the PQA to convene MTM leaders on evidence-based priorities for measurement.[15]

Comment: Another commenter urged CMS to increase transparency regarding the costs of the MTM program (that is, how much plans are saving versus how much they are allocating to pay pharmacists for the services) and whether Part D plans are incentivized to offer robust MTM services.

Response: We remind commenters that per § 423.153(d)(5)(ii), even though a Part D sponsor must disclose to CMS the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others, reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

Comment: A commenter stated that CMS's proposals in the December 2022 proposed rule to add Part D measures to the Star Ratings, such as the focus on polypharmacy measures, may present an opportunity to improve MTM. The commenter felt that the proposed changes to the MTM program eligibility criteria would expand eligibility but do not address the issue of providing MTM to Medicare beneficiaries who could truly benefit from it.

Response: We thank the commenter for the feedback. We agree that MTM programs may present an opportunity to improve plan performance in Star Ratings measures such as polypharmacy and help with overall improvement of medication use among Part D beneficiaries. Refer to Section VII.B.3 for discussion about the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Concurrent Use of Opioids and Benzodiazepines (COB) Measures.

Comment: Some commenters encouraged CMS to continue to examine policy options that expand access to MTM and improve patient outcomes and, in particular, to release the findings from the fifth and final year of the Part D Enhanced MTM model (Enhanced MTM model). Another commenter suggested that the Enhanced MTM model can address alarming trends of medication underuse and overuse. The commenters also encouraged CMS to collaborate with interested parties to leverage the findings from the Enhanced MTM model and identify best practices in MTM to scale nationally, as well as to guide future reforms before taking action to change MTM.

Response: CMS will continue to examine policy options within our authority that expand access to MTM and improve patient outcomes. In February 2023, CMS released the fifth and final evaluation report for the Enhanced MTM model available at: *https://www.cms.gov/priorities/innovation/innovation-models/enhancedmtm.* We will continue to review the results of the Enhanced MTM model and collaborate with interested parties to identify best practices and lessons learned that may help improve the traditional Part D MTM programs. We disagree that CMS should leverage model findings or run additional analyses before making changes to the Part D MTM programs, as our disparities analysis discussed in the December 2022 proposed rule identified specific eligibility gaps that need to be addressed. As such, we are moving forward with finalizing modifications to the MTM targeting criteria in this final rule.

Comment: A commenter urged CMS to require plan sponsors to report MTM enrollee data and analyze the data using demographic information to measure and address disparities among the enrollees.

Response: Plan sponsors are currently required to report MTM program beneficiary-level data to CMS through the Part D Reporting Requirements (OMB 0938–0992). We used these data and other program data, including demographic information, to perform the MTM disparities analysis. Furthermore, researchers may request access to a Part D MTM data file through ResDAC[16] which could be linked to encrypted beneficiary and demographic variables in the CCW.

Comment: Many commenters suggested that if CMS finalizes the combination of changes as proposed, the updated eligibility criteria should be implemented on a delayed or phased-in basis. Commenters stated that such an approach would provide plan sponsors with the additional time necessary to build up staffing, processes, and infrastructure over several years; to coordinate with other internal programs to manage medications for the core chronic diseases; and to ensure local networks can accommodate the increased volume. Commenters who suggested delays were concerned about implications for costs and the timing for bid submissions as well as the need for operational enhancements. Commenters who advocated for a phased-in approach suggested ways to finalize one or more of the proposed MTM criteria changes over time on an annual basis. Another commenter suggested that CMS take a stepwise approach by first finalizing the proposal to require plan sponsors to target all 10 core chronic diseases to evaluate how MTM engagement improves, and then allow some flexibility in how plans target within broad therapeutic categories.

Response: We appreciate the suggestions to implement the proposed changes using a delayed or phased-in approach. However, we do not agree that such an approach is necessary because CMS is finalizing the proposed changes with modification, and—as discussed later in this preamble—the resulting program size will be about 35 percent smaller than originally estimated in the December 2022 proposed rule. The reduced program size mitigates the need for a phased-in approach to accommodate the new MTM enrollees. Additionally, the changes will be effective in 2025 rather than 2024 as initially proposed, which will provide additional time for Part D plan sponsors to build up the necessary infrastructure to support the anticipated increase in MTM enrollment.

We now address comments on specific aspects of the proposed eligibility criteria changes and describe our rationale for finalizing the proposed changes with modifications.

[15] *https://www.pqaalliance.org/mtm-convenes.*

[16] Information on the Part D MTM Data File available through ResDAC at: *https://resdac.org/cms-data/files/part-d-mtm.*

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 three chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. In the current CMS MTM guidance (See HPMS Memorandum Correction to Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023), CMS identifies nine core chronic diseases.

In the December 2022 proposed rule, we proposed 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 proposed to codify the nine core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. We explained that the current flexibility afforded to plans to identify enrollees with multiple chronic diseases had led to variability across plans and was a main driver of eligibility gaps and inequitable beneficiary access to MTM services. Under our proposal to codify the 10 core chronic diseases, plan 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 the December 2022 proposed rule, CMS also solicited 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.[17] We sought comments 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. We were 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 solicited 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.

The comments we received on our proposed policies with respect to targeting of core chronic diseases are summarized below along with our responses.

Comment: Many commenters supported the proposal to add HIV/AIDS to the list of core chronic diseases. Several commenters applauded CMS for recognizing and attempting to address disparities within the HIV/AIDS community. Other commenters pointed out that antiretroviral medications are not only high cost but part of complex regimens that require frequent monitoring and re-evaluation. Supporters of this proposal also emphasized the importance of MTM services for HIV/AIDS patients with many comorbidities.

Response: CMS thanks the commenters for their support for the proposal to add HIV/AIDS as a core chronic disease. We agree that Part D enrollees with HIV/AIDS often have complex Part D drug regimens where medication adherence is critical, very high Part D drug costs, and multiple comorbidities. In addition, these individuals are more likely to be members of populations affected by health disparities. For these reasons and for the reasons discussed in the December 2022 proposed rule, we are finalizing the proposal to include HIV/AIDS in the core chronic diseases at § 423.153(d)(2)(iii).

Comment: Many commenters were opposed to including HIV/AIDS as a core chronic disease and expressed concerns regarding the potential of MTM programs disrupting therapy that is already being closely monitored by a specialized team. Other commenters were concerned that the pharmacists reviewing the drug regimen for individuals with HIV/AIDS may not have the specialized training needed. One commenter suggested additional qualifications to identify high-risk medication use among this population. Lastly, some commenters stated that the data needed for a successful CMR for this population, including lab values, are not always available.

Response: We acknowledge that Part D sponsors, especially PDPs, may not always have complete and up to date information at the time of a CMR, but the CMR may provide the opportunity to obtain additional information regarding an individual's current therapy. As discussed in CMS MTM guidance (See HPMS Memorandum Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023), a CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver, and/or prescriber. The CMR is designed to improve patients' knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self-manage their medications and their health conditions. MTM services should be complementary, not disruptive, to services furnished by the beneficiary's care team, and an MTM provider may make referrals or recommendations to the beneficiary's prescribers to resolve potential medication-related problems or optimize the beneficiary's medication use.

The CMS analysis presented in the December 2022 proposed rule found that, on average, Part D enrollees with HIV/AIDS have 4 core chronic diseases (including HIV/AIDS), take 12 Part D covered drugs (including eight maintenance drugs), and incur $40,490 in Part D annual drug spend. Because beneficiaries with HIV/AIDS are likely to have complex drug regimens and are at increased risk of medication-related problems, they could benefit from MTM to improve medication use. Despite having multiple chronic diseases, taking multiple Part D drugs, and incurring high Part D drug costs, many of these individuals were not eligible for MTM because their plan did not target HIV/AIDS or did not target enough of their other chronic diseases. However, we also found that HIV/AIDS was more likely to be targeted by plans (about 10 percent of plans in 2021) than any other non-core chronic disease, suggesting that these plans have already recognized the value of offering MTM services to this population.

Comment: Some commenters questioned whether data privacy policies and state laws would allow Part D sponsors to engage in data sharing with MTM vendors. Others voiced concern over the sensitive nature of an

[17] *https://www.whitehouse.gov/cancermoonshot/CE.*

HIV/AIDS diagnosis and that giving MTM providers access to enrollees' health information would increase the risk of a data breach or cause member concerns over privacy.

Response: CMS requires Part D sponsors to comply with all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information per § 423.136. Those laws may require additional steps for Part D sponsors to share information with MTM providers, such as obtaining beneficiary consent. In establishing the requirement to include HIV/AIDS as a core chronic disease, we do not intend to change or modify any legal obligations that entities may have under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule or any other law. Regarding the potential for data breaches, we expect plan sponsors and their MTM providers to have appropriate safeguards in place to protect personal health information for beneficiaries with HIV/AIDS just as they do for enrollees with other diseases or medication regimens.

Comment: Many commenters supported the proposal to require Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. Some of these commenters emphasized the importance of MTM services for beneficiaries with diseases such as ESRD and mental health conditions. We received suggestions to expand the inclusion of Alzheimer's disease on the list of core chronic diseases to include neurodegenerative diseases (including multiple sclerosis) and/or other dementias such as Lewy Body disease or frontotemporal lobar degeneration and pain as core chronic diseases.

Other commenters who supported the proposal suggested that requiring the 10 core chronic diseases should provide more consistency in MTM eligibility between plans and broaden beneficiaries' eligibility for MTM in each plan.

Response: We thank the commenters for their supportive comments regarding our proposal to require sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. We are finalizing that proposal at § 423.153(d)(2)(iii). Plan sponsors will be required to target all 10 core chronic diseases beginning January 1, 2025. This change will address the concerns we discussed in the December 2022 proposed rule regarding increasingly restrictive criteria implemented by plan sponsors (for example, by targeting select core chronic diseases), which have been one of the main drivers of reduced eligibility rates for MTM. By reducing the variability in targeting criteria across plans, we will eliminate situations where enrollees meet the requirement in § 423.153(d)(2)(i)(A) of having three chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. This change will also ensure that plan sponsors are targeting all of the chronic diseases specified in the statute at section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act, along with certain other chronic diseases that we have identified as prevalent in the Part D population and commonly treated with Part D drugs. This reduced variability should also allow CMS to more accurately estimate program size when calculating burden and assessing impact.

We will continue to analyze chronic diseases 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, including those suggested by the commenters, and may consider proposing additional core chronic diseases such as neurodegenerative diseases and/or other dementias in future rulemaking. Although we are not adding pain as a core chronic disease in this final rule, we remind sponsors that as of January 1, 2022, they are now required to target ARBs as defined at § 423.100 for MTM enrollment. We also note that plan sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic diseases.

Comment: Many commenters opposed the proposal to require Part D sponsors to include all core chronic diseases to identify beneficiaries who meet the targeting criterion of having multiple chronic diseases. Some commenters suggested that CMS limit core diseases to those that do not require specialized training or requested extra time to hire specialized staff. Another commenter urged CMS to continue to allow plan sponsors to have flexibility to establish a targeted population within the 10 core chronic diseases. Other commenters wanted to limit the core chronic diseases to those that are easily identified using Part D claims only or to those associated with the Star Ratings medication adherence measures. A commenter noted that even though the core chronic diseases are not entirely new, the requirement for sponsors to include all of them will necessitate IT development for file transfer of medical claims data, adding complexity, as most plans utilize only prescription drug claims data to identify members. For example, the commenter mentioned that to target beneficiaries with many of the core chronic diseases, plans will need to submit diagnosis codes from medical claims to MTM vendors in order to identify such members. Another commenter was concerned that lab work or other relevant data points may not be easily accessible by the plan's MTM pharmacist. One commenter felt that MTM pharmacists are not in the best position to positively impact (and may detract from) a beneficiary's care with a CMR and routine TMR assessments for ESRD.

Response: Plan sponsors' flexibility to target select core chronic diseases was a main driver of inequitable access to MTM in the Part D program that we addressed in our proposed changes to the Part D MTM requirements in the December 2022 proposed rule. CMS strongly believes pharmacists or other qualified MTM providers with extensive knowledge and training of prescribed medications are in an excellent position to impact a beneficiary's medication use, regardless of the chronic diseases they have or the Part D drugs they take. For instance, beneficiaries with ESRD typically have multiple co-morbidities being treated with multiple Part D drugs which may benefit from a CMR and assessment for dose adjustments due to kidney function. If a beneficiary requires more specialized services or coordinated care, MTM may be a means to identify and refer the beneficiary to such services. We also remind commenters that the eligibility criteria, including core chronic diseases, help identify beneficiaries who may be at increased risk of medication-related problems. However, MTM services should not focus only on the core chronic diseases or drugs within classes used to treat those diseases. For example, the CMR should include a review of all of the MTM enrollee's prescription medications, OTC medications, herbal therapies, and dietary supplements. As they do today, plan sponsors should optimize their targeting algorithms and methods using data available to them to identify enrollees who are eligible for MTM. Some plan sponsors may need to update their IT systems or workflows to expand the use of data sources available to them to better optimize their targeting methods.

Comment: Some commenters requested clarification on whether all diseases included under the 10 core chronic disease categories must be targeted, or whether plans will have the flexibility to choose specific diseases within the core chronic diseases. A few

commenters were concerned that requiring targeting for all core chronic diseases removes sponsors' ability to customize their MTM program to target members they deem well-suited for MTM services.

Response: Plan sponsors must target all 10 core chronic diseases, including all conditions within each core chronic disease. As discussed in the proposed rule, our analysis found that a significant proportion of the Part D population that we identified as having three or more core chronic diseases and using eight or more drugs were not eligible to be targeted for MTM, and variation in plan-specific targeting criteria (for example, plans targeting fewer than all of the core chronic diseases) was a key driver of gaps in eligibility for MTM. By reducing the variability in targeting criteria across plans, we can significantly reduce situations where enrollees meet the requirement in § 423.153(d)(2)(i) of having three chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. The proposal to require plan sponsors to target all 10 core chronic diseases, which we are finalizing in this rule, 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. Plan sponsors will still have the flexibility of targeting additional chronic diseases beyond the core diseases codified in this rule.

Comment: A commenter wanted CMS to provide greater specificity when codifying core diseases. For example, they asked that CMS clarify how ''other chronic lung disorders'' are defined under respiratory disease and how ''chronic/disabling mental health conditions'' are defined under mental health.

Response: CMS does not have guidance for plan sponsors to define or code core chronic diseases such as ''other chronic lung disorders'' or ''chronic/disabling mental health conditions.'' Sponsors should retain documentation supporting their eligibility criteria determinations.

Comment: In response to our request for information and feedback on including additional diseases, such as cancer, in the list of core chronic diseases, a couple of commenters supported including cancer as a core chronic disease. One commenter felt it would align well with some pharmacies' specialty pharmacy offerings and clinical services. We also received some comments opposed to adding cancer as a core chronic disease for MTM program eligibility. Some commenters indicated that complex cancer treatment needs timely, on-going monitoring by specialists with expertise across Part B and Part D medications (for which data sets may or may not be available) and may not be best managed by Part D MTM programs through annual CMRs or by pharmacists without specialized training. Other commenters noted that specialty pharmacies, which dispense the majority of oral cancer medications (including specialty pharmacies within oncology clinics), already provide monitoring or counseling for their oncology patients. A commenter was concerned that beneficiaries with cancer may find MTM outreach to be intrusive and unwanted, and another was concerned with patient sensitivity when in remission. Another commenter that opposed including cancer as a core chronic disease noted that beneficiaries who meet the current MTM eligibility criteria who are also taking oncology drug(s) would still benefit from the MTM review for side effects, safety, and potential drug-drug interactions.

Response: Equitable access to cancer screening and targeting the right treatments for cancer patients is a top priority under the goals of the Cancer Moonshot. However, while section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act provides us the authority to specify and include other chronic diseases, after consideration of the comments received in response to the RFI, we do not believe it would be appropriate to add cancer to the core chronic diseases specified in § 423.153(d)(2)(iii) in this final rule. We agree that including cancer may be potentially disruptive to the medication management that is already a part of standard clinical practice in oncology and specialty centers. Moreover, it is unclear that cancer patients' needs can be met through Part D MTM program annual CMRs centered on Part D medication use delivered by MTM pharmacists who typically lack the specialized training in oncology. Cancer treatment goals are often different than the goals for treatment of the other chronic diseases included in Part D MTM program (such as diabetes), where MTM may be used to review and stabilize drug regimens that are likely to be long term. In contrast, many cancers involve a high utilization of physician-administered Part B drugs and frequently changing medication regimens. Also, cancer is not currently commonly targeted by Part D plans as a chronic disease for their MTM program eligibility.

While we are not adding cancer as a core chronic disease at this time, we emphasize that some cancer patients may still be eligible for MTM based on meeting the eligibility criteria. We encourage Part D plans and MTM providers to seek opportunities to promote cancer screening where possible for MTM enrollees and to coordinate with specialty cancer programs to develop medication safety recommendations for cancer patients. In support of the Cancer Moonshot, CMS has initiated other activities, such as the Enhancing Oncology Model (EOM),[18] which is designed to test how best to place cancer patients at the center of high-value, equitable, evidence-based care. CMS has also adopted rules providing payment for principal illness navigation services to help patients and their families navigate cancer treatment and treatment for other serious illnesses.[19]

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 eight is the maximum number of Part D drugs a Part D plan sponsor may require for targeted MTM enrollment. In accordance with the technical HPMS User Guide for the MTM Program submission module, sponsors are permitted to include all Part D drugs, all Part D maintenance drugs, or specific drug classes.

We proposed to revise § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require for targeted enrollment from eight to five for plan years beginning on or after January 1, 2024. As discussed in the preamble to the December 2022 proposed rule, while there is no consensus definition of polypharmacy in terms of the use of a certain number of medications or medication classes concurrently, the proposed change would ensure the MTM program continues to focus on more individuals with complex drug regimens and increased risk of medication therapy problems. In addition, although we proposed changes to the targeting criteria with respect to the number of Part D drugs, we noted that the CMR described in § 423.153(d)(1)(vii)(B) should continue to include review of all prescription medications, OTC medications, herbal therapies, and dietary supplements.

We also proposed to add a new provision at § 423.153(d)(2)(iv) to

[18] *https://www.cms.gov/newsroom/press-releases/biden-administration-announces-new-model-improve-cancer-care-medicare-patients.*

[19] *https://www.cms.gov/newsroom/press-releases/cms-finalizes-physician-payment-rule-advances-health-equity?ref=upstract.com.*

require all sponsors to include all Part D maintenance drugs in their targeting criteria. 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 proposed 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 solicited public comment on our proposed parameters for defining maintenance drugs, including potential additional sources for making such determinations.

Below, we address comments on the proposed revisions to the maximum number of covered Part D drugs a plan sponsor may require and our proposal to require sponsors to include all Part D maintenance drugs in their targeting criteria. We also describe our rationale for finalizing the proposed changes with modifications.

Comment: Many commenters supported the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. These commenters supported overall expansion of the MTM program, which they believed would increase medication safety. A commenter who supported the proposal suggested additional targeting criteria, such as targeting individuals taking high-risk medications.

Response: We appreciate the support for this proposal. However, we remind commenters that section 1860D–4(c)(2)(A)(ii) of the Act requires plans to target beneficiaries taking multiple covered Part D drugs. We note, however, that plans retain the flexibility to enroll beneficiaries taking high-risk medications in their MTM programs through expanded eligibility, even if they do not meet the statutory criteria for targeted enrollment. In addition, high-risk medication use may be addressed through MTM interventions.

Comment: Many commenters opposed the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Commenters were concerned that MTM would not be as useful for beneficiaries with less complex drug regimens and suggested that beneficiaries should qualify for MTM enrollment based on higher pill burdens and more complicated medication regimens. One commenter stated that a typical enrollee with three or more chronic diseases takes between seven and 10 medications and recommended retaining the current maximum number of drugs at eight. Another commenter suggested initially only decreasing this threshold from eight to five drugs for sponsors that use specific classes of drugs in their criteria, and then fully implementing the proposed change for all plan sponsors the following year.

Response: After consideration of these comments, and the general comments expressing concerns about increased burden and costs, current pharmacy and vendor shortages, and other resource challenges due to the combination of MA and Part D program policy changes plan sponsors must implement over the next several years, we are not finalizing our proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs at this time. We are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs at eight (see § 423.153(d)(2)(i)(B)). Plan sponsors will maintain the flexibility to set a lower threshold (between two and eight Part D drugs) for targeting. This will maintain the MTM program focus on beneficiaries with the most complex drug regimens and will result in a more moderate expansion of the MTM program size. Additionally, our decision not to finalize this aspect of our proposed modifications to the MTM eligibility criteria is supported by CMS' data analysis included in the December 2022 proposed rule (87 FR 79542–79546). We found that the beneficiaries identified as having 3 or more core chronic conditions and using 8 or more drugs who were not eligible for MTM took on average eight to nine Part D drugs, which suggests that the number of Part D drugs criterion is not a main driver of MTM eligibility disparities under our current policies. This change to our proposal allows us to respond to commenters' concerns regarding the potential impact of reducing the maximum number of Part D drugs from eight to five, while still addressing the barriers to eligibility posed by the increasingly restrictive plan criteria (for example, by targeting select core chronic diseases or drugs) and the high cost threshold, which were identified in our analysis as the main drivers of reduced eligibility rates for MTM. CMS will continue to monitor the impact of the number of Part D drugs criterion on MTM eligibility rates and consider whether to propose any changes in future rulemaking.

Comment: No commenters specifically supported or opposed the proposal to include all Part D maintenance drugs in the targeting criteria. One commenter requested clarification on whether specific Part D drug classes could still be targeted. A few commenters recommended either Medispan or First DataBank as sources for identifying maintenance drugs but wanted discretion to determine which one they use.

Response: We appreciate the comments. As we stated in the December 2022 proposed rule, under the proposed modifications to the MTM eligibility criteria, Part D 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 at a minimum. However, plans would retain the option to expand their criteria by targeting additional Part D drugs or all Part D drugs. While we proposed that plan sponsors would be required to identify Part D maintenance drugs using information contained within a widely accepted drug database, such as Medi-Span or First Databank, we expressly stated that Part D plans would retain discretion to determine which database to use.

We are finalizing the proposed provision at § 423.153(d)(2)(iv) with modification. Specifically, we are revising the regulation text to clarify that sponsors must include all Part D maintenance drugs and to expressly state that Part D sponsors retain the flexibility to include all Part D drugs in their targeting criteria. Additionally, we are finalizing the requirement that sponsors rely on information contained within a widely accepted, commercially or publicly available drug information database to identify Part D maintenance drugs. We are also updating the text of this provision to reflect that these requirements will apply beginning on January 1, 2025. We are not finalizing the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs at this time.

d. Annual Cost Threshold

Section 1860D–4(c)(2)(A)(ii) of the Act specifies that beneficiaries targeted 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 2024 is $5,330. 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. 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 diseases and are taking multiple Part D drugs. 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.

In the December 2022 proposed rule, we proposed to amend the regulation at § 423.153(d)(2)(i)(C) to set the MTM cost threshold at the average cost of five generic drugs, as defined at § 423.4, for plan years beginning on or after January 1, 2024. Under this proposal, CMS would calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C). As noted in the December 2022 proposed rule, based on 2020 data, the average annual cost of five generic drugs was $1,004. In the proposed rule, CMS indicated that 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. Based on 2022 PDE data analyzed after publication of the December 2022 proposed rule, the average annual cost of five generic drugs was $994. In the December 2022 proposed rule, we noted that in subsequent years, the MTM cost threshold would be published in the annual Part D Bidding Instructions memo.

Below, we address comments on the proposed revisions to the annual cost threshold and describe our rationale for finalizing a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs, which will be applicable beginning January 1, 2025.

Comment: Many commenters opposed the proposal to set the MTM cost threshold at the average cost of five generic drugs. While many of these commenters agreed that the current MTM cost threshold is too high, they opposed our proposal to base the cost threshold on the average cost of five generic drugs due to the estimated impact on MTM program size. Instead, some commenters supported a less significant cost threshold reduction. A few commenters suggested that the cost threshold is irrelevant as the number of drugs, not their cost, is a key metric. A health plan commented that over 40 percent of its enrollees would have annual drug costs that meet the proposed MTM cost threshold and suggested that the overarching aim should instead be to continue targeting enrollees who are at risk for polypharmacy. This commenter cited a study suggesting the range of rates of ambulatory elderly patients who experience adverse drug reactions is 20 to 25 percent and that targeting a much larger percentage of Medicare Advantage membership to enroll in an MTM program may divert the focus from the population that would most benefit from program inclusion. Other commenters did not recommend decreasing the cost threshold to align with annual average generic drug costs because that would target beneficiaries who would not benefit from a CMR consultation regarding cost savings opportunities. Another commenter suggested that CMS consider increasing the annual cost threshold, instead of decreasing it, to better account for inflation in the prescription drug market and allow plans to have greater capacity to target MTM services to high need members.

Some commenters suggested alternative proposals for lowering the MTM cost threshold. One commenter suggested CMS seek insight from the industry, such as the PQA, on how best to adjust the cost threshold. A few commenters recommended alternative approaches to establish the cost threshold, such as commensurate with the average cost of eight generic drugs, a specific dollar amount, the cost of a mix of brand and generic drugs as many beneficiaries take at least one brand drug, or an incremental approach to decreasing the cost threshold, starting with the annual cost of six or seven drugs.

Response: After considering the comments and suggestions we received, we are persuaded to finalize a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs beginning January 1, 2025. This revised cost threshold methodology aligns with our decision not to finalize our proposal to reduce the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Lowering the cost threshold removes a significant barrier to MTM enrollment, but setting the threshold at the cost of eight (instead of five) generic drugs yields a more moderate program size expansion, which will address commenters' concerns about cost and burden. Encouraging the use of generic or lower cost drugs when medically appropriate remains a pillar of the Part D program. Under our final policy, beneficiaries meeting the criteria of having multiple chronic diseases and taking multiple Part D drugs, but who are taking lower cost generic alternatives, may now be targeted for MTM enrollment. MTM enrollees, especially those with high drug costs, may continue to benefit from cost saving opportunities from CMRs. However, even if a CMR consultation does not result in cost savings, there are other benefits of CMRs beyond cost savings.

Comment: Many commenters requested clarification regarding the MTM cost threshold calculation, including which five generic drugs will be used to determine this new cost threshold; what methodology CMS will use to select the drugs; how authorized generics, biosimilars, or un-branded biologics factor into the determination; whether the proposed methodology would utilize the top five utilized generic drugs by prescription volume or the top five generic drugs by plan paid amount; whether the calculation includes or excludes generic specialty medications; whether there is a process to detect outlier national drug codes (NDCs) to ensure they are not included in the calculation; and whether the cost of five generic drugs is per 30-day supply of medication. A few commenters asked if the proposed cost threshold would be expected to increase or decrease annually. Another commenter suggested that CMS reevaluate cost data for generic drugs, as costs of many generic drugs have increased since 2020 due to global supply chain issues after the COVID–19 pandemic. One commenter asked if enrollees would be required to receive the generic drugs only.

Response: The average daily cost of one generic drug was calculated as total gross drug cost divided by total days supply for all Part D covered generic drugs utilized by all Part D enrollees during the plan year. The average daily

cost of one generic drug was then multiplied by eight drugs and 365 days to compute an average annual cost of eight generic drugs. The total gross drug cost used in this calculation is the sum of the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, during the relevant plan year and includes both plan paid amounts and enrollee cost sharing. This calculation does not include the cost of biologic products or authorized generics. Compound drug claims are also excluded.

Beginning January 1, 2025, CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug as determined 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 provision at § 423.104(d)(2)(iv)(C). CMS will analyze the PDE data for all Part D covered generic drugs utilized by all Part D enrollees during the plan year to calculate the average daily cost of one generic fill and multiply the average daily cost of one generic fill by 365 days to determine an annual amount. Therefore, the cost threshold may change annually. Although average costs for all Part D covered generic drug fills will be used to calculate the MTM cost threshold, a beneficiary would not be required to only take generic drugs to meet the eligibility criteria for MTM, and beneficiary-specific drug costs may vary from the averages.

For example, based on 2022 PDE data, the average annual cost of eight generic drugs was $1,591. If the MTM threshold were set at this amount, plans would be required to target beneficiaries who are likely to incur annual covered Part D drug costs greater than or equal to $1,591 (across all Part D drugs they take, not just generic drugs) and meet the other MTM targeting criteria for having multiple chronic diseases and taking multiple Part D drugs for enrollment in their MTM program.

Based on analysis of 2023 PDE data, the MTM cost threshold will be $1,623 for 2025. The MTM cost threshold will be published in the annual Part D Bidding Instructions memo for future years.

Following consideration of the comments received on the cost threshold, as well as on the maximum number of Part D drugs plans may target, we are finalizing a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs as defined at § 423.4. This new cost threshold methodology will be applicable beginning January 1, 2025.

e. Summary

After consideration of the comments received, we are finalizing proposed changes to the Part D MTM program eligibility requirements with the modifications discussed. The changes are effective January 1, 2025 and are summarized below.

- We are finalizing the provision at § 423.153(d)(2)(iii) that Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of this provision at § 423.153(d)(2)(iii), we are codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS, for a total of 10 core chronic diseases. The 10 core chronic diseases are: (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). Sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic diseases.
- We are not finalizing the proposal at § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from eight to five at this time. We are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs as eight at § 423.153(d)(2)(i)(B). Part D sponsors will maintain the flexibility to set a lower threshold (a number between two and eight Part D drugs) for targeting beneficiaries taking multiple Part D drugs. We may revisit the maximum number of Part D drugs (eight) a sponsor may require in future rulemaking.
- We are finalizing the provision at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs in their targeting criteria with minor modifications to the regulatory text to clarify that sponsors must include all Part D maintenance drugs and to provide flexibility for sponsors to include all Part D drugs in their targeting criteria. However, sponsors will not be permitted to limit the Part D maintenance drugs included in MTM targeting criteria to specific Part D maintenance drugs or drug classes. We are also finalizing the requirement at § 423.153(d)(2)(iv) that, for the purpose of identifying Part D maintenance drugs, plans must rely on information in a widely accepted, commercially or publicly available drug information database.
- We are finalizing the provision at § 423.153(d)(2)(i)(C) with modification to set the MTM cost threshold at the average cost of eight generic drugs, as defined at § 423.4. CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

We believe these final policies will allow us to address specific gaps identified in MTM program eligibility by reducing marked variability across plans and ensuring more equitable access to MTM services; better align with Congressional intent while focusing on beneficiaries with complex drug regimens; and keep the program size manageable. The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce as a whole. With these changes, we estimate that the number and percent of Part D enrollees eligible for MTM will increase from 3.6 million (7 percent of Part D enrollees based on actual 2022 MTM enrollment data) to a total of 7.1 million (13 percent of Part D enrollees estimated using 2022 data), which is smaller than the estimated program size of 11 million beneficiaries in the December 2022 proposed rule. Burden estimates and impacts are discussed in sections X. and XI. of this proposed rule, respectively.

2. Define ''Unable To Accept an Offer To Participate'' in a Comprehensive Medication Review (CMR)

In guidance issued annually, CMS has consistently stated that we consider a beneficiary to be unable to accept an offer to participate in a CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. In the December 2022 proposed rule, we proposed 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.

We received the following comments on this proposal, and our responses follow:

Comment: A commenter voiced their support for our proposal.

Response: CMS appreciates the commenter's support.

Comment: A few commenters opposed or voiced concerns about the proposal, stating that many beneficiaries who are not cognitively impaired request that their caregiver or a trusted family member participate in the CMR on their behalf. For example, one commenter mentioned hearing impairment as a barrier for the beneficiary receiving the CMR directly from the provider. Another commenter pointed out that many beneficiaries receive MTM services in long-term care facilities where nurses who manage their medications should be allowed to participate in the reviews on the beneficiary's behalf. They argued that caregivers should be allowed to participate in the CMR as long as HIPAA Privacy Rule policies are not violated, and proper documentation is maintained.

Response: Our proposal to codify the definition of ''unable to participate'' does not preclude beneficiaries from inviting other individuals to join them for the CMR. MTM enrollees may continue to include caregiver or family member participation during the MTM process, though we emphasize that MTM is a beneficiary-centric program. Instead, this rule codifies the definition of ''unable to participate,'' which is different from a beneficiary requesting a CMR to be completed with another individual. Generally, we expect the beneficiary being ''unable to participate'' due to cognitive impairment to be an uncommon designation that should be reported through the Part D Reporting Requirements (OMB 0938–0992). We will continue to monitor the percentages of beneficiaries who are unable to accept a CMR offer for outlier rates, and sponsors should retain documentation supporting any instance in which a beneficiary is designated as ''unable to participate'' in their reported data.

CMS would also like to remind plan sponsors that they are expected to put in place safeguards against discrimination based on the nature of their MTM interventions. Hearing impairment should not prevent a beneficiary from receiving MTM services. Relevant federal regulations for MTM programs may include Federal Communications Commission requirements for accessibility, as defined in 47 CFR part 64 Subpart F; Americans with Disabilities Act (ADA): Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities, 28 CFR part 36; Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title, 45 CFR Part 92; Section 504 of the Rehabilitation Act, Nondiscrimination on the Basis of Handicap in Programs or Activities Receiving Federal Financial Assistance, 45 CFR part 84; and 21st Century Communications and Video Accessibility Act (CVAA). Part D sponsors should also refer to the standards for communications and marketing found at 42 CFR 423.2267(a).

After consideration of the comments received, we are finalizing the definition of a ''unable to accept an offer to participate'' in a CMR as proposed at § 423.153(d)(1)(vii)(B)(2) to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

3. Requirement for In Person or Synchronous Telehealth Consultation

As discussed in the December 2022 proposed rule, we proposed 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. As discussed in the December 2022 proposed rule, 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.

We received the following comments on this proposal, and our responses follow:

Comment: Several commenters supported clarifying the regulatory language on the use of telehealth. A few commenters expressly stated that their support for the proposal was conditioned on ''telehealth'' including a telephone option. Another commenter expressed concern regarding lower levels of engagement due to fewer people wanting in-person interactions in a pharmacy setting and fewer people answering their phone, even when it is their local pharmacy calling.

Response: We thank these commenters for their feedback and confirm that telephonic communication meets the definition of synchronous telehealth. We believe updating the regulation to clarify that a CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth, will ensure that beneficiaries receiving a CMR via telehealth have the same opportunities to engage with their providers in real time as beneficiaries who receive a CMR in-person. Sponsors are encouraged to offer multiple methods of engagement since beneficiaries may prefer in-person or telehealth interactions.

After consideration of the comments received, we are finalizing the proposed revisions to § 423.153(d)(1)(vii)(B)(1)(i) without modification.

4. MTM Program Technical Changes

In the December 2022 proposed rule, we proposed several technical changes to the regulation text related to the Part D MTM program. At § 423.4, we proposed 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 proposed to remove the dash and replace it with a period to be consistent with other paragraph headings in Subpart D. We proposed 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 proposed to replace ''MTMP'' with ''MTM program'' to ensure that the terminology is used consistently.

We did not receive any comments regarding these changes and are finalizing these MTM program technical changes as proposed.

F. Part D Subcontractors May Terminate Only at the End of a Month (§ 423.505)

At § 423.505(i), we proposed 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 proposed that this prior notice be required in contracts with FDRs that perform critical functions on the sponsor's behalf, as described in the December 2022 proposed rule. 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. We are finalizing this provision as proposed.

As discussed in the December 2022 proposed rule preamble, 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.

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 the 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 was terminated in the middle of March 2021 due, in part, to the PDP's 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 proposed 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 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). Because Part D sponsors are paid prospectively and in units of no less than one calendar month, they and their subcontractors should be able to negotiate arrangements for access to covered Part D drugs in no less than 1-month increments by, for example, requiring Part D 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 Part D sponsors because mid-month terminations have been very rare to date.

The proposed provision at new paragraph (6) requires 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 failing to receive necessary drugs or incurring unnecessary costs.

We received comments on this proposal, which are summarized below, and respond to them as follows.

Comment: One commenter requested clarification on whether the proposed rule was applicable to terminations initiated by Part D sponsors or limited to terminations initiated by FDRs.

Response: The proposed rule would only apply to terminations initiated by FDRs. Part D sponsors would remain free to terminate their FDRs mid-month or on less than 60 days' notice if their contracts with FDRs permit such terminations. CMS notes that any sponsor seeking to terminate an FDR mid-month or on short notice would remain accountable for ensuring that its enrollees continue to receive uninterrupted Part D benefits in compliance with the statute, regulation, and its contract with CMS.

Comment: A few commenters expressed support for the proposal but requested that CMS include an exemption for terminations initiated by Part D sponsors based on fraud or member harm.

Response: CMS appreciates commenters' support. We note that the proposed rule would not limit Part D sponsors' ability to terminate their FDRs for any reason. Therefore, sponsors' ability to terminate FDR contracts based on fraud or member harm would be unaffected by the proposed rule.

After considerations of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the provision as proposed with one grammatical edit regarding capitalization.

G. Application of 2-Year Ban on Reentering the Part D Program Following Non-Renewal (§§ 423.507 and 423.508)

In the December 2022 proposed rule, we proposed 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 entering into 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 entering into a new or expanded PDP contract in the PDP region(s) they exited and would not prevent them from entering into a new or expanded contract in another region(s). We also proposed to clarify that the 2-year exclusion applies whenever a PDP sponsor terminates all of its plan 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 or mutual termination, 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 or mutual termination 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.

As described in the proposed rule, 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 the Part D sponsors choosing to stop serving LIS beneficiaries would be only one 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 proposed to modify §§ 423.507(a) 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 2 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 2-year ban.

Similarly, we proposed to apply our policy limiting the offering of plans at the PDP region level for 2 years to mutual terminations under § 423.508. We proposed 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 received a comment on this proposed provision.

Comment: The commenter was generally supportive of the proposal and of exempting EGWP plans from the 2-year ban following nonrenewal or mutual termination. The commenter requested that we also exempt PDP PBPs and contracts terminated as part of a consolidation of plans and contracts after an acquisition.

Response: We appreciate the commenter's support for our proposal. We understand the commenter's concern regarding the application of the 2-year ban following a PDP consolidation, but do not believe any modification of the proposal is necessary because the termination of a PDP contract as part of a consolidation would not trigger the 2-year ban so long as the surviving contract continued to offer PDP PBPs in the affected regions. A consolidation occurs when two or more PDP contracts operated by the same sponsor or by sponsors that are subsidiaries of the same parent organization combine into a single contract. Consolidations often occur after the acquisition of a sponsor by a parent organization that has subsidiaries that offer PDP PBPs in the same region as the acquired sponsor. CMS limits the

number of PDP PBPs that a sponsor (or subsidiaries of the same sponsor) can offer to three plans per region under § 423.265(b)(3) and consolidations are often required to comply with this requirement following an acquisition. So long as the contract into which the plans are consolidated continues to offer PDP PBPs in the affected region(s), the sponsor (or the sponsor's parent organization) is not exiting the region and therefore would not be subject to the 2-year ban on reentering the region.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to those comments, we are finalizing the provision as proposed with minor grammatical and formatting changes.

H. Crosswalk Requirements for Prescription Drug Plans (§ 423.530)

1. Overview and Summary

In the December 2022 proposed rule, we proposed 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 defined plan crosswalks and crosswalk exceptions; codified the circumstances under which enrollees can be transferred into different PDP PBPs from year to year; established the circumstances under which enrollees can be transferred into PDP PBPs offering different types of prescription drug coverage (''basic'' or ''enhanced alternative'' coverage); established the circumstances under which enrollees can be transferred due to contract consolidations of PDPs held by subsidiaries of the same parent organization; and provided protections against excessive premium increases resulting from crosswalks. We also proposed to limit the ability of PDP sponsors to create new PDP PBPs to replace non-renewing PBPs under certain circumstances.

We requested comment on whether and under what circumstances we should permit crosswalks from PBPs offering basic prescription drug coverage to PBPs offering enhanced alternative 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 limitations we should place on premium and cost increases for enrollees who are crosswalked between different PBPs. We were 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 proposed to codify the current procedures that a Part D sponsor must follow when submitting a crosswalk or crosswalk exception request.

2. 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 codifying 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 proposed to define a plan crosswalk as the movement of enrollees from one PDP PBP to another PDP PBP. We noted that this definition is consistent with current policy and with the definition of crosswalks for MA plans, codified at § 422.530(a)(1).

We proposed at § 423.530(a)(2)(i) through (iii) to adopt the crosswalk prohibitions in current CMS subregulatory guidance, described in the ''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 to the CMS website at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionbDrugCovbContra/Downloads/Guidance-for-Prescription-Drug-Plan-PDP-Renewals-and-Non-Renewals-.pdf*. First, we proposed 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 proposed to prohibit crosswalks that split enrollment of one PBP into multiple PBPs. Third, we proposed to prohibit crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage.

In the preamble to the December 2022 proposed rule, we noted that, 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 the December 2022 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 enhanced alternative PBP might therefore have to pay more than they would in the available basic PBP, even if the enhanced alternative PBP has a lower overall premium. 87 FR 79602. Therefore, we proposed to continue our current policy in order to protect LIS-eligible beneficiaries from unanticipated premium increases.

We solicited comments on whether and under what circumstances to allow crosswalks from PBPs offering basic prescription drug coverage to enhanced alternative coverage. CMS was 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 proposed at § 423.530(a)(3) to require sponsors seeking crosswalks to comply with rules in §§ 423.506 and 423.507 governing renewals and non-renewals, respectively. This requirement is consistent with the requirement for MA plan crosswalks codified at § 422.530(a)(3). We also proposed 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. Finally, we proposed 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 would ensure that the process for enrollment in employer group health or waiver plans is not disrupted by this proposed rule.

3. Mandatory Crosswalks (§ 423.530(b))

We proposed 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. As discussed in the December 2022 proposed rule preamble, this requirement would continue to apply to PBPs offering both enhanced alternative and basic coverage and would continue to facilitate evergreen enrollment as required by section 1851(c)(3)(B) of the Act. We also noted that the proposal was consistent with the requirements for MA renewal crosswalks codified at § 422.530(b)(1)(i).

4. Plan Crosswalk Exceptions (§ 423.530(c))

We proposed at § 423.530(c) to classify consolidated renewal and contract consolidation crosswalks as ''crosswalk exceptions.'' We proposed to define ''consolidated renewals'' and ''contract consolidations'' consistent with the current policy described previously in section IV.AD.2. of the December 2022 proposed rule. We proposed to codify our current policy for the two types of plan crosswalk exceptions with some modifications.

For consolidated renewals, we proposed to codify current policy at § 423.530(c)(1)(i) through (iv) with modifications that balance concerns for beneficiaries in non-renewing plans losing coverage with concerns about market stability and limiting unexpected premium increases. Specifically, we proposed that:

- 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.

We also proposed four major modifications to current policy with respect to consolidated renewals:

- 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 other requirements of § 423.530;
- At § 423.530(c)(1)(v), 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;
- At § 423.530(c)(1)(vi), to prohibit plan crosswalks 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; and
- At § 423.530(c)(1)(vii), to prohibit sponsors that fail to request and receive a plan crosswalk exception from offering a new enhanced alternative PBP in the same service area for the contract year after they non-renew an enhanced alternative PBP.

As discussed in the preamble to the December 2022 proposed rule, 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 solicited 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 also requested 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. Finally, we sought comment on alternatives to using the base beneficiary premium. Potential alternatives included 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.

These four proposed changes represented a significant shift from current policy. As such, we solicited comments on alternative approaches. Possible alternatives included, but were 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 also proposed 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. We proposed 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.

We proposed the following significant changes to current policy with respect to contract consolidations:

- At § 423.530(c)(2)(v), require plan crosswalks from non-renewing PBPs offering enhanced alternative coverage into the PBP that would result in the lowest premium increase; and
- At § 423.530(c)(2)(vi), 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.

5. Procedures for Requesting Plan Crosswalks (§ 423.530(d))

We proposed 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 proposed that a Part D sponsor must submit all mandatory plan crosswalks in writing through the bid submission process in HPMS by the bid submission deadline. We further proposed that a Part D sponsor must submit all plan crosswalk exceptions by the plan crosswalk exception request deadline announced annually by CMS. 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 ultimately request a crosswalk exception through the crosswalk exception functionality in HPMS in accordance with the deadline announced annually. 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 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.

6. Response to Comments

We are finalizing crosswalk requirements for PDPs at § 423.530 without modification, as discussed in the responses to comments that follow.

Comment: Several commenters asked that we consider plan characteristics other than total premiums when determining which plan or plans beneficiaries could be crosswalked into. They noted that crosswalks can result in more changes than just a change in premium, including changes to cost sharing and formulary drugs. They suggested that CMS consider factors such as the beneficiary OOPC estimate in the plan bid and the formulary composition and structure, in addition to the plan premium, when assessing which PBP beneficiaries can be crosswalked into in consolidated renewal and contract consolidation scenarios.

Response: CMS acknowledges and shares the concerns that commenters expressed regarding the impact that changing PBPs can have on individual beneficiaries' costs and access to drugs. However, it is very difficult to predict which formulary will be best for the greatest number of beneficiaries. CMS reviews all formularies to ensure that they contain the required number of Part D drugs from each therapeutic category and class and an appropriate range of strengths and dosages of those drugs, that utilization management requirements (including prior authorization and step therapy requirements) are appropriate, and that the formularies otherwise meet all Part D requirements. While this ensures that all plans offer appropriate coverage of and access to Part D drugs, individual beneficiaries may find that certain formularies offer better coverage of, or pricing for, the drugs they utilize. CMS does not currently have a methodology to determine whether a particular approved formulary will be ''better'' for a group of beneficiaries than another approved formulary, given the variety of ways that an individual beneficiary may deem a certain formulary ''better'' and the diversity of needs from one beneficiary to the next. For instance, one beneficiary may find inclusion of utilization management to be off-putting whereas another values a low tier placement. Despite these hypotheticals, premiums have been shown to be a key factor in plan choice for beneficiaries.

Each plan does have an estimated OOPC value, which estimates the average monthly out-of-pocket costs for enrollees in a PBP. But while that is a useful bid review and actuarial tool, the actual costs incurred by beneficiaries are highly variable because they are based on characteristics—including but not limited to LIS status, health status, medications used, pharmacies chosen—that vary widely among beneficiaries. Premiums, on the other hand, are uniform for all beneficiaries. We believe that attempting to use other information, including OOPC and formulary composition and structure, to determine which plans beneficiaries may be crosswalked into is too complicated to be practical at this time.

CMS will continue to encourage beneficiaries to investigate the cost and benefits of available Part D plans during each Annual Election Period (AEP). Beneficiaries can use Medicare Plan Finder and other tools to assess which plans offer the combination of premiums, cost sharing, pharmacy networks, and formulary coverage that best meets their individual needs. Part D sponsors will continue to be required to send Annual Notices of Change (ANOCs), Evidences of Coverage (EOCs) and other materials as described in § 423.2267(e) to all beneficiaries enrolled in their plans before the AEP so that beneficiaries will have information such as formulary coverage, cost sharing, and prior authorization requirements to use when comparing plans.

Comment: A few commenters requested that CMS provide a special election period (SEP) to beneficiaries subject to consolidated renewal and contract consolidation crosswalks. These commenters believe that beneficiaries do not always realize how their Part D benefits are changing for the new year and that they may benefit from an SEP so they may select new plans after the new plan year begins.

Response: CMS acknowledges commenters' concerns. However, plan premiums, cost sharing, and formularies can significantly change year-to-year even when beneficiaries are not being crosswalked into a new PBP. CMS does not believe that beneficiaries subject to crosswalks, particularly with the safeguards we are finalizing in this rule, are any more vulnerable to not understanding the resulting changes to their Part D benefits than beneficiaries who are continuing in the same PBP without being crosswalked. Therefore, we do not believe an SEP is appropriate for crosswalked beneficiaries. Crosswalked beneficiaries will receive the same notice of changes—the ANOC—that all other beneficiaries in continuing Part D coverage will receive before the AEP. They will also receive all other required material, including the EOC and Summary of Benefits, which provide details about premiums, deductibles, and cost sharing for the new plan. CMS continues to encourage all beneficiaries to compare available coverage offerings during every AEP.

Comment: One commenter representing a Part D plan requested that CMS delay the effective date of the crosswalk provisions until after the premium stabilization protections in the Inflation Reduction Act of 2022 (''IRA'') go into effect.

Response: CMS notes that the premium stabilization provisions of the IRA, which provide a mechanism to limit the growth in the base beneficiary premium (used to calculate the plan-specific base premium) to a 6 percent increase compared to the previous year, went into effect for plan year 2024. There is therefore no need to further

delay implementation of the crosswalk provisions based on the concerns expressed by this commenter.

Comment: Some commenters opposed limiting consolidated renewal and contract consolidation crosswalks to those that would result in the lowest premium increase and barring such crosswalks when they would result in premium increases greater than 100 percent. These commenters believed plans needed greater flexibility in determining the appropriate plan into which to crosswalk members. Specifically, they wanted CMS to take formulary structure, cost sharing, and network composition into account. They also expressed concern over the effect that the implementation of various provisions of the IRA would have on plan premiums. They were concerned that the cost sharing limits for insulin and certain adult vaccines (which went into effect in 2023), ending beneficiary cost sharing for covered Part D drugs during the catastrophic phase of the benefit (effective in 2024), and the new beneficiary Part D out-of-pocket spending limit (effective in 2025), among other provisions, will create unanticipated volatility in Part D premiums. They requested that if CMS finalizes these requirements as proposed, we delay implementation of the provisions of the proposed crosswalk regulation that limit premium increases until at least 2026 to give the market time to adjust to the changes.

Response: As we noted in the preamble to the proposed rule, crosswalks have rarely resulted in premium increases greater than 100 percent. We therefore do not think it is necessary to preserve ''flexibility'' for plans to implement such crosswalks in the future. We also note that the proposed crosswalk requirements would grant plans more flexibility in some respects by allowing them to choose to non-renew an enhanced alternative plan without crosswalking enrollees into another plan. Earlier in this preamble, we also pointed out in response to a comment requesting that CMS consider factors other than premiums in assessing the appropriateness of a proposed crosswalk that taking formulary comparisons or anticipated out-of-pocket costs into account would not be practical at this time.

CMS understands the commenters' concerns about the unanticipated consequences of changes to the Part D program required by the IRA. As discussed earlier in this preamble in response to another comment, the IRA includes a mechanism to limit the growth in the base beneficiary premium (used to calculate the plan-specific base premium) for Part D plans starting on January 1, 2024. The 2024 Part D premiums reflect both the IRA's premium stabilization provisions and its provisions limiting cost sharing for covered insulin products and recommended adult vaccines and ending beneficiary cost sharing for covered Part D drugs during the catastrophic phase of the benefit. Rather than increasing, the average total monthly premium for Medicare Part D coverage was projected to decrease 1.8 percent from $56.49 in 2023 to $55.50 in 2024 for 2024.[20] We anticipate that premiums will continue to remain stable as the IRA is fully implemented.

While we do not believe it is necessary to suspend or delay these elements of the proposed rule, we will delay implementation of this proposal until January 1, 2026 to allow time for necessary system updates to be made to the CMS systems for the 2026 bid cycle that commences in June 2025. To the extent that commenters are concerned about the burden of implementing the new crosswalk requirements while adjusting to major changes under the IRA, this delay should allay their concerns.

Comment: A commenter recommended allowing LIS beneficiaries to be crosswalked from basic to enhanced alternative plans when the premium for the enhanced alternative plan is lower than for the available basic plan. The commenter believed that this would save the government money by reducing LIS payments. The commenter alternatively recommended allowing the creation of LIS-only plans to be offered by all sponsors to address the unique needs of LIS beneficiaries.

Response: We thank the commenter for their input. While we acknowledge that a lower premium enhanced alternative plan may indeed lower the LIS subsidy the government would pay for an LIS beneficiary enrolled in the plan, the commenter's recommendation does not address the primary reason we prohibit such crosswalks. As we discussed in the proposed rule, CMS can only provide the LIS for the portion of the monthly beneficiary premium attributable to basic coverage, pursuant to § 423.780(b)(1)(i). 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. The commenter's recommendation for an LIS-only offering is beyond the scope of our proposal.

Comment: One commenter requested clarification on how CMS would compare a premium increase to the base beneficiary premium when considering whether to allow a crosswalk that would result in a premium increase of over 100 percent compared to the non-renewing plan's total plan premium. The commenter interpreted the requirement proposed for § 423.530(c)(1)(vi) and (2)(vi) to compare the base beneficiary premium to the premium increase amount, not to the total premium after the increase. The commenter interpreted our proposal to allow a consolidated renewal or contract consolidation crosswalk if the premium increase were the same or lower than the base beneficiary premium and asked for confirmation of that interpretation.

Response: The commenter's interpretation of the proposed language is accurate. CMS will evaluate compliance with this requirement by comparing the anticipated premium increase for crosswalked beneficiaries to the base beneficiary premium.

Comment: One commenter expressed concern that ''forcing'' plans to crosswalk members into certain plans would negatively impact current members in those plans by increasing premiums based on the claims history of the crosswalked members.

Response: This commenter appears to confuse our current crosswalk policy, which does mandate crosswalks when sponsors non-renew an enhanced alternative plan while continuing to offer PDP PBPs in a service area, with the proposal, which would no longer require such crosswalks. Under the proposed policy, sponsors could choose not to perform a consolidated renewal crosswalk for members from a non-renewing enhanced alternative PDP PBP into another PBP under the same contract. CMS would bar the sponsor from creating a new enhanced alternative plan to replace the non-renewing one if the sponsor opted not to crosswalk membership from the non-renewed plan, but CMS would no longer require plans to perform such crosswalks.

Comment: A commenter expressed general support for codifying the

[20] CMS Press Release, ''Medicare Advantage and Medicare Prescription Drug Programs to Remain Stable in 2024,'' September 26, 2023, available at *https://www.cms.gov/newsroom/press-releases/medicare-advantage-and-medicare-prescription-drug-programs-remain-stable-2024*.

crosswalk requirements as proposed because it would create clear requirements for PDP crosswalks. They asked that CMS consider other factors in the PDP market that create incentives for plan sponsors to consolidate PDP offerings and that may result in unnecessary premium increases. Specifically, the commenter asked that CMS make modifications to the Prescription Drug Hierarchical Condition Category (Rx-HCC) Risk Adjustment Model to enhance the predictive power of the tool and ensure more appropriate reimbursement to plan sponsors. They believe that the current model may no longer adequately mitigate against plan sponsors' incentives to engage in risk selection. They specifically asked that CMS take steps to reduce the lag time for including updated claims data in the model to not more than three years.

Response: CMS appreciates the commenter's support for this proposed rule. CMS does not believe there are additional factors related to premium increases that could be addressed through our proposed crosswalk requirements. The comments regarding the Rx-HCC Risk Adjustment Model are beyond the scope of this proposal.

After considerations of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the plan crosswalk provisions as proposed but with minor grammatical and formatting changes and a delayed effective date from January 1, 2025 to January 1, 2026.

I. Call Center Text Telephone (TTY) Services (§§ 422.111 and 423.128)

We proposed to make a technical change by modifying §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) to require a plan's call center to establish contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services, rather than establishing contact with a TTY operator within 7 minutes on no fewer than 80 percent of incoming calls. Our proposed change was intended to remove any ambiguity that might result from our use of the term ''TTY operator,'' because our intent was to ensure a beneficiary could establish contact with a customer service representative within 7 minutes. 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, when MA organizations and Part D sponsors use 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.

We received several comments supporting and no comments opposing this proposal. CMS thanks those in support of our proposal. For the reasons outlined in the proposed rule, we are finalizing the revision as proposed.

J. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503)

1. Overview and Summary

In the December 2022 proposed rule, we summarized the history of our treatment of substantially incomplete applications and proposed 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 also proposed to codify longstanding criteria for determining that an application is substantially incomplete. We are finalizing these provisions as proposed.

We proposed 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), we proposed to codify that we do 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 our 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 proposed 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 the MA or Part D application. Pursuant to §§ 422.501(c) and 423.502(c), entities seeking to qualify as an MA organization (or to qualify to offer a specialized MA plan for special needs individuals (a SNP)) and/or Part D sponsor to must fully complete all parts of a certified application, in the form and manner required by CMS. Applications for service area expansions are subject to the same rules and review processes because 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 proposed 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 information and/or materials, including failing to include required content or responsive material for any section of the application, in their submission by the application 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 include (by uploading to the application system) 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 reasonably 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 an 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 might 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 proposed 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 to file an 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.

We do 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. We believe 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 received comments on this proposal, which are summarized below:

Comment: A commenter expressed support for the proposal and appreciated the clarifications regarding what constitutes a substantially incomplete application.

Response: CMS appreciates the commenter's support.

Comment: Several commenters generally supported the proposal but requested clarification on what documentation would be sufficient to indicate that an application was not substantially incomplete. A few commenters specifically requested further clarification on what constitutes evidence that a state licensure application was filed. One commenter wanted additional clarity on what evidence would indicate that a plan made ''best efforts'' to complete an application.

Response: CMS appreciates the commenters' support. As summarized from the proposed rule earlier in this section, an example of a substantially incomplete application is one where the organization failed to provide evidence of state licensure or documentation that the state received a licensure application from the applicant before the CMS application due date. When an entity submits, with the MA application, documentation that the entity has filed a complete state licensure application with the appropriate state before the CMS MA and Part D application due date, CMS will not determine that the application is substantially incomplete based on a failure to provide responsive materials in the state licensure section of the MA application. (However, all other portions of the MA application must also be complete for CMS to review and evaluate the application.) Documentation to demonstrate that the entity has applied for the appropriate state licensure for its MA application could consist of a copy of the application and a receipt or other documentation that the application was sent to and received by the state before the CMS MA and Part D application due date. MA organizations must be licensed in the state(s) of the service area(s) covered by the application in order to ultimately have their application approved by CMS.

CMS did not propose and does not currently use a ''best efforts'' standard for determining whether an application is substantially incomplete. In the proposed rule (87 FR 79520), we described an example of an MA applicant submitting a list of providers that was so few that CMS could only conclude that that applicant had not even made a good faith effort to create a complete network by the application deadline, which is key to demonstrating the ability to provide adequate access to covered services. For example, an application would be substantially incomplete if it only included a single pharmacy in the retail pharmacy network submission, regardless of how much effort the organization submitting the application put into enrolling pharmacies in the network. An organization that was acting in good faith would not have filed an application wherein they certified they met application requirements if they had not been able to enroll more than a single pharmacy by the application deadline. While CMS recognizes that it can be challenging for an organization to prepare to offer MA and Part D plans, CMS expects any organization filing an application to have already made sufficient progress in its preparations to provide responsive materials to all parts of the application.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the revisions to §§ 422.502(a)(3) and 423.503(a)(4) as proposed without substantive modification. The final regulation text includes minor stylistic changes.

K. Expanding Network Adequacy Requirements for Behavioral Health

Section 1852(d)(1) of the Act allows 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 assures continuity in the provision of benefits. Further, our regulation at § 422.112(a), requires that a coordinated care plan maintain a network of appropriate providers that is sufficient

to provide adequate access to covered services to meet the needs of the population served. To establish standards for these requirements, CMS codified network adequacy criteria and access standards 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. Further, as part of the ''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) proposed rule, hereinafter referred to as the ''January 2022 proposed rule,'' we solicited comments through a Request for Information (RFI), regarding challenges in building MA behavioral health networks and opportunities for improving access to services. In response to the RFI, 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. As a result, in the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, which appeared in the **Federal Register** on April 12, 2023, (88 FR 22120) hereinafter referred to as the ''April 2023 final rule,'' CMS finalized the addition of two new specialty types to the provider-specialty types list at § 422.116(b)(1), Clinical Psychology and Clinical Social Work, to be subject to the specific time and distance and minimum provider number requirements used in CMS's network adequacy evaluation.

While our regulation at § 422.116(b)(3) authorizes the removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not implement a process in § 422.116 to add new provider types without rulemaking. In a continued effort to address access to behavioral health services within MA networks, we proposed to add to the list of provider specialties at § 422.116(b) and add corresponding time and distance standards at § 422.116(d)(2).

In addition to meeting the network adequacy evaluation requirements, MA organizations are required at § 422.112(a) to maintain and consistently monitor their provider networks to ensure they are sufficient to provide adequate access to covered services that meet the needs of enrollees. This also helps MA organizations maintain a complete and accurate health plan provider directory as required under §§ 422.111(b)(3) and 422.120(b). The Health Plan Management System (HPMS) provides MA organizations with access to the ''Evaluate my Network'' functionality, which allows MA organizations the opportunity to test their provider networks against the evaluation standards in § 422.116 outside of a formal network review. The ''Evaluate my Network'' functionality provides MA organizations the ability to test their networks using the standards in § 422.116(a)(2) in different scenarios, including at the Plan Benefit Package (PBP) level, to consistently monitor whether their provider networks are meeting the current network adequacy standards. We encourage MA organizations to utilize the HPMS ''Evaluate my Network'' tool to monitor their PBP-level active provider networks and keep abreast of any network issues that could hinder access to care for enrollees. We also remind MA organizations to report any compliance issues or significant changes in their provider network to their CMS Account Manager.

With the revisions applicable to coverage beginning January 1, 2024, MA organizations are required to demonstrate that they meet network adequacy for four behavioral health specialty types: psychiatry, clinical psychology, clinical social work, and inpatient psychiatric facility services. The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328) amended the Act to authorize payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) and by a Mental Health Counselor (MHC), effective January 1, 2024. Specifically, section 4121 of the CAA amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for MFT services (as defined in section 1861(lll) of the Act) and MHC services (as defined in section 1861(lll) of the Act). MA organizations are required to cover virtually all Part B covered services. As such, these new services must be covered as defined and furnished, respectively, by MFTs, as defined in section 1861(lll)(2) of the Act, and MHCs, as defined in section 1861(lll)(4) of the Act. As a practical matter, MA organizations need to ensure access to these new Medicare-covered services that can only be provided by these types of individual providers and therefore must contract with these types of providers in order to furnish basic benefits as required by section 1852 of the Act (when furnished by different providers, the services will be supplemental benefits covered by the MA plan).

In addition, we discussed in the April 2023 final rule that the responses CMS received to the January 2022 proposed rule RFI emphasized the importance of expanding network adequacy standards to include other outpatient behavioral health physicians and health professionals that treat substance use disorders (SUDs) to better meet behavioral health care needs of enrollees. Medicare fee-for-service claims data for 2020 shows that Opioid Treatment Program (OTP) providers had the largest number of claims for SUD services during that timeframe. At the time of publishing our April 2023 final rule, we indicated that while we were not able to finalize adding a combined specialty type called ''Prescribers of Medication for Opioid Use Disorder,'' which included OTPs and Medication for Opioid Use Disorder (MOUD) waivered providers to the facility-specialty type list in § 422.116(b)(2) as proposed, we would consider the appropriateness of setting network adequacy standards for OTPs in future rulemaking.

Considering the statutory changes to section 1861 of the Act as mentioned, and our interest in establishing network adequacy standards for SUD providers, CMS proposed to amend the MA network adequacy requirements to address the new provider types and SUD provider types through a combined behavioral health specialty type to include MFTs, MHCs, OTPs, Community Mental Health Centers and other behavioral health and addiction medicine specialty providers that will help us enhance behavioral health access for enrollees. This is consistent with the explanation in our April 2023 final rule that setting a meaningful access standard for the OTP specialty type will be possible under a combined behavioral health specialty type.

CMS is committed to improving access to behavioral health care services for enrollees in the MA program. The

CMS Behavioral Health Strategy,[21] aims to improve access and quality of mental health care and services, including access to substance use disorder prevention and treatment services. We proposed to extend network adequacy requirements to additional behavioral health and substance use disorder providers and facilities by adding time and distance and minimum provider number requirements for a combined provider category. Specifically, we proposed to add Outpatient Behavioral Health as a new type of facility-specialty in § 422.116(b)(2) and to add Outpatient Behavioral Health to the time and distance requirements in § 422.116(d)(2). For purposes of network adequacy evaluations under § 422.116, Outpatient Behavioral Health can include, MFTs (as defined in section 1861(lll) of the Act), MHCs (as defined in section 1861(lll) of the Act), OTPs (as defined in section 1861(jjj) of the Act), Community Mental Health Centers (as defined in section 1861(ff)(3)(B) of the Act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners, and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities. Per § 422.2, the term ''provider'' means (1) any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and (2) any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. Although we are not using the term ''provider'' specifically here in listing the type of healthcare professionals that we expect to be available to furnish services in order to count for purposes of the proposed new network evaluation standard, all applicable laws about the practice of medicine and delivery of health care services must be met and specific healthcare professionals must be appropriately licensed or certified to furnish the applicable services.

We proposed to add this combined facility-specialty type instead of adding individual provider-specialty types for a few reasons. First, data from the U.S. Department of Labor, Bureau of Labor Statistics show that currently MFTs and MHCs are generally providing services in outpatient behavioral health settings, such as community mental health centers, substance abuse treatment centers, hospitals, and some private practices. [22] [23] These types of clinical settings offer a fuller range of services and usually provide access to additional providers, such as advanced practice nurses and physician assistants who provide counseling and other therapeutic services to individuals with behavioral health conditions; our review of the Place of Service codes recorded on professional claims for behavioral health services in the Medicare FFS program illustrates this. In addition, currently, there are a limited number of (if any) claims in the Medicare FFS program from MFTs and MHCs; combining the MFT and MHC provider types into the ''Outpatient Behavioral Health'' facility type provides time for CMS to develop additional data as FFS claims are submitted by MFTs and MHCs to show patterns of access to these provider types across the country. CMS needs such claims and utilization data to support the development of time and distance standards for these particular provider-specialty types. Finally, categorizing these provider specialties as a facility type is consistent with our practice under § 422.116, wherein physical therapy (PT), occupational therapy (OT), and speech therapy (ST) providers have traditionally been categorized as facility types, even though care is typically furnished by individual health care providers. These provider types (that is, PT, OT, ST) are reported for network adequacy purposes under facility specialty types on Health Service Delivery (HSD) tables.

As mentioned previously, the statutory change under the CAA will allow MFTs and MHCs to bill Medicare directly for services provided beginning January 1, 2024. We acknowledge that these provider types may not always be located in facilities and provide facility-based services. As such, we will continue to monitor the appropriateness of maintaining this proposed new behavioral health specialty type as a facility-specialty type (that is, under § 422.116(b)(2)) for network adequacy review purposes. Similarly, as the list [24] of OTPs enrolled in Medicare continues to expand, we will continue to monitor whether network adequacy for OTPs is best measured under a combined facility type for the purpose of network adequacy reviews. Thus, we may engage in future rulemaking to revise this requirement if the landscape of providers changes such that access will be best evaluated separately for MFTs, MHCs, or OTPs instead of under the one facility-specialty type we proposed in this rule. Any related changes will be proposed in future rulemaking. We proposed that MA organizations are allowed to include on their facility HSD tables for the proposed new facility type (Outpatient Behavioral Health) the following: contracted individual practitioners, group practices, or facilities that are applicable under this specialty type. We proposed that MA organizations may not submit a single provider for purposes of meeting the Outpatient Behavioral Health requirement if they have already submitted that provider under another specialty. For example, MA organizations would not be permitted to submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty and as an Outpatient Behavioral Health facility.

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 facility specialty types under § 422.116(b)(2), we proposed base time and distance standards in each county type for the new specialty type as follows:

[21] *https://www.cms.gov/cms-behavioral-health-strategy.*

[22] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Marriage and Family Therapists, at *https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm* (visited *July 03, 2023*).

[23] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Substance Abuse, Behavioral Disorder, and Mental Health Counselors, at *https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm* (visited *July 06, 2023*).

[24] *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers.*

TABLE CK-1: MAXIMUM TIME AND DISTANCE STANDARDS:

Provider/ Facility type	Large Metro		Metro		Micro		Rural		Counties with Extreme Access Considerations (CEAC)	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

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 **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). Further, we explained in the February 2020 proposed rule how CMS determines the minimum number requirement for all provider and facility specialty types, which is now codified in § 422.116(e). We codified at § 422.116(e)(2)(iii) that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. Because we had previously established paragraph (e)(2)(iii) to refer to all facility types listed in paragraph (b)(2)(ii) through (xiv) and proposed to add Outpatient Behavioral Health as a facility type at paragraph (b)(2)(xiv), we did not propose any revisions to paragraph (e)(2)(iii). We followed the analysis and methodology described in the February 2020 proposed rule to develop the time and distance standards that we proposed to apply to the new behavioral health facility-specialty type described here. However, we utilized updated data, including outpatient facility and professional Part B claims data from August 1, 2021, through July 31, 2022, to inform our proposed standard.

Finally, as we indicated in the April 2023 final rule, 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 (88 FR 22170). Per § 422.116(d)(5), MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers 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. Currently, § 422.116(d)(5) specifies 14 specialty types for which the 10-percentage point credit is available. Because we understand from stakeholders who commented on our April 2023 final rule that they were supportive of usage of the 10-percentage point credit for behavioral health specialty types, we also proposed to add the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types 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 solicited comments on this proposal. Our responses to the comments received are outlined below.

Comment: Numerous commenters supportive of our proposal to improve behavioral health network adequacy standards in MA plans. Commenters commended CMS for continuing to work towards increasing access to behavioral health and improving health equity for MA enrollees through these efforts. However, several commenters expressed concerns regarding the proposal to consolidate several specialty and facility types into a new single category for purposes of evaluating network adequacy in MA. Specifically, commenters expressed concern that combining mental health (MH) and substance use disorder (SUD) specialties into one category may diminish the distinct access needs for these individual specialty types and that the combined standard as proposed was too broad.

Recognizing the specialized nature of these services, commenters advocated for differentiating MH and SUD network adequacy requirements. Many commenters recommended establishing separate specialty categories for ''Outpatient Mental Health'' and ''Outpatient Substance Use Disorder,'' while other commenters suggested separate categories for Opioid Treatment Programs (OTPs), and separate standards for MFTs and MHCs. Commenters stated that the creation of separate standards for these specialties would allow for more visibility for enrollees of the availability of these services and better meet enrollees' behavioral health and SUD needs.

Response: We thank commenters for their support and careful consideration of our proposal. We agree with stakeholders that establishing policies that improve network adequacy is critical to improving access to behavioral health care, including access to substance use disorder prevention and treatment services in MA.

We indicated in the November 2023 proposed rule that setting meaningful network adequacy standards that include MFTs, MHCs, and OTPs at this time is possible under a combined behavioral health specialty type. We determined this through our review of U.S. Department of Labor data and the Place of Service codes recorded on certain professional claims data from 2017–2020 for behavioral health services in the Traditional Medicare program, which indicate that MFTs and MHCs are generally providing services in outpatient behavioral health settings.[25] [26] As we have also stated in our April 2023 final rule, setting a meaningful access standard for the OTP specialty type would be possible under a combined behavioral health specialty type. We are taking this approach to provide additional time for CMS to collect the specific claims and utilization data for MFTs and MHCs. We may engage in future rulemaking to establish specific time and distance

[25] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Marriage and Family Therapists, at *https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm* (visited July 03, 2023).

[26] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Substance Abuse, Behavioral Disorder, and Mental Health Counselors, at *https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm* (visited July 06, 2023).

standards for these specialties separately. More robust claims and utilization data will help us to evaluate how enrollees are accessing these benefits in Medicare Advantage and Traditional Medicare. Additionally, we noted our intent to continue monitoring the availability of OTPs across the country and determine whether network adequacy for OTPs is best measured separately from the broader Outpatient Behavioral Health facility-specialty type.

The Outpatient Behavioral Health facility-specialty type will include individual practitioner and facility providers that furnish psychotherapy and/or counseling services to individuals with mental health or substance use disorders. Our review of certain Traditional Medicare claims data from 2017–2020 (Place of Service codes, Type of Bill codes, CCN codes, and Revenue Center codes) indicates that facility types treat individuals with both mental health disorders and substance use disorders. While the individual providers may specialize in either mental health or substance use disorder treatment, many of the facility providers will offer a variety of services and provider types to meet the range of enrollees' behavioral health needs. In the absence of more robust utilization and claims data, the Outpatient Behavioral Health specialty type should be effective for use in our MA plan network adequacy standards at this time.

Finally, § 422.116(a) requires that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year (see section II.A. of this final rule regarding the definition of ''network-based plan''). In addition, § 422.112 requires MA coordinated care plans (which are network-based plans) to ensure covered services are accessible and available to enrollees. Therefore, MA organizations must always provide access to all covered services whether or not access to a particular provider specialty is specifically evaluated by CMS through our network adequacy standards.

Comment: Many commenters requested that CMS revise the proposed Outpatient Behavioral Health time and distance standards to align with those already established for Qualified Health Plans (QHPs). Commenters emphasized that shortening the standards to reflect the benchmarks set for QHPs would potentially benefit enrollees as behavioral health services may be needed more frequently. Commenters emphasized that aligning these standards would provide consistent and adequate access across Federal programs and support operational needs of health plans.

Response: We are interested in aligning policies across Medicare, Marketplace, and Medicaid wherever practicable. However, for MA plans, CMS utilizes data on the unique health care utilization patterns and geographic locations of Medicare beneficiaries and providers and facilities to set the MA network adequacy time and distance as well as the minimum provider and facility number requirements under 42 CFR 422.116. Therefore, at this time, we believe the requirements we proposed, and are finalizing in this rule, are appropriate for providing access and meeting the health care needs of the specific beneficiary population served by this program.

Comment: Multiple commenters expressed concerns that MA provider network adequacy standards could be met utilizing Nurse Practitioners (NPs), Physician Assistants (PAs), and Clinical Nurse Specialists (CNSs) within the new Outpatient Behavioral Health facility-specialty type. Commenters suggested that the absence of clear and transparent criteria for incorporating these provider types could result in the creation of ''ghost networks,'' and one commenter referred to ghost networks as networks where providers may be listed in a provider directory without actively treating patients for behavioral health. Further, commenters indicated that these provider types (NPs, PAs, CNSs) might lack the necessary skills, training, or expertise to effectively address the mental health and substance use disorder needs of enrollees.

Response: We appreciate the feedback regarding the inclusion of NPs, PAs, and CNSs within the new Outpatient Behavioral Health facility-specialty type. We reiterate that the revisions to § 422.116(b) and (d), as proposed and finalized, mandate that for purposes of network adequacy evaluation, providers, including NPs, PAs, and CNSs, must regularly furnish or will regularly furnish behavioral health counseling or therapy services, including psychotherapy or the prescription of medication for substance use disorders, in order for those providers to be included in the new facility specialty Outpatient Behavioral Health. Further, by defining the new facility specialty Outpatient Behavioral Health so broadly, we expect that these facilities will generally deliver a comprehensive array of services. This includes services from MFTs, MHCs, OTPs, community mental health centers, addiction medicine physicians, and outpatient mental health and substance use treatment facilities.

Recognizing the diverse capabilities of NPs, PAs, and CNSs in providing services to beneficiaries, CMS acknowledges the concerns raised by stakeholders regarding the use of NPs, PAs, and CNSs to satisfy the Outpatient Behavioral Health network adequacy standards without verifying their qualifications to address and actual practice of addressing behavioral health or SUD needs. To address this, we are finalizing a clarification in § 422.116(b)(2)(xiv) to limit when MA organizations may list an NP, PA, or CNS, for purposes of network evaluation under the Outpatient Behavioral Health facility-specialty type. Specifically, the final rule establishes a standard to identify when an NP, PA, or CNS regularly furnishes, or will furnish, behavioral health counseling or therapy services, including psychotherapy or medication prescription for SUDs.

For an NP, PA, or CNS to satisfy the Outpatient Behavioral Health network adequacy standards, the NP, PA, and/or CNS must have furnished certain psychotherapy or SUD prescribing services to at least 20 patients within the previous 12-months. The 20-patient threshold is consistent with the minimum denominator requirement of several quality measures, including many that are measured at the clinician-level in the Merit-based incentive payment system (MIPS) in Traditional Medicare. If the threshold is an important minimum for individual practitioners being held accountable for the quality of care delivered in Traditional Medicare, then having a similar threshold here for when the practitioner ''regularly furnishes'' behavioral health care will ensure that the NP, PA, or CNS is providing a meaningful amount of behavioral health counseling or therapy services, including psychotherapy or medication prescription for SUDs. In addition, we believe the 12-month period timing will provide the best reflection of current practice and is a sufficient time predicter of the next year's practice by the provider.

Further, this standard supports the intent that a provider who is an NP, PA or CNS, must ''regularly furnish or will regularly furnish'' behavioral health

services. This will help ensure that organizations only include providers who have expertise in delivering services to be counted for network adequacy purposes. The 12-month and 20 patient threshold demonstrates that an NP, PA, or CNS has provided the applicable services on an ongoing basis, and it will also provide a standard for organizations that wish to utilize these provider types for network adequacy evaluation.

As part of this minimum threshold for identifying that a specific PA, NP and CNS regularly furnishes behavioral health services, we are adopting specific requirements in new paragraphs (b)(2)(xiv)(A) and (B) for how this threshold will be used. The list of psychotherapy or SUD prescribing services to be used for this purpose will be identified by CMS in the Health Service Delivery (HSD) Reference File (described in § 422.116(a)(4)(i)). CMS will identify the applicable services in the HSD Reference File, using HCPCS code(s), narrative descriptions, or something sufficiently similar to specify the necessary type of services on an annual basis.

The MA organization must annually verify that this standard is met by each individual NP, PA and/or CNS it intends to submit for purposes of the Outpatient Behavioral Health facility type by analyzing reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data. This analysis must be performed at least annually using a recent 12-month period and must be completed before the MA organization includes the NP, PA and/or CNS to CMS for purposes evaluation of the MA organization's network for the Outpatient Behavioral Health facility type. If there is insufficient evidence of these provider types having previous practice experience sufficient to meet the threshold of 20 patients within a recent 12-month period, MA organizations must have a reasonable and supportable basis for concluding that the provider will meet the threshold in the next 12 months. If an NP, PA, or CNS is new to independent practice (and therefore doesn't have the appropriate claims record in previous years), has received psychiatry or addiction medicine specialized training, and is listed as a psychiatry or addiction medicine NP, PA, or CNS on public-facing websites, this would be a reasonable and supportable basis for concluding that the practitioner would meet the requirement in the next 12 months, and therefore able to be utilized towards meeting network adequacy standards for Outpatient Behavioral Health. We are establishing these requirements in § 422.116(b)(2)(xiv)(B)(1) and (2).

This requirement is designed to prevent MA organizations from including providers in their networks submitted to CMS for review that are lacking a history of delivering or intent to deliver behavioral health services, thereby improving the reliability of MA organization's network's once operational. Further, this requirement will help MA organizations identify the requisite services that NPs, PAs, and CNSs must provide. MA organizations may be required to demonstrate, in the specified form and manner requested by CMS, that the MA organization has verified the service provision threshold. These criteria aim to enhance transparency and accountability while preventing the formation of ''ghost networks.'' This ensures that beneficiaries receive care from providers with proven expertise in treating mental health and substance use disorders.

Finally, we are also adopting a requirement, at § 422.116(b)(2)(xiv)(B)(3) that an MA organization must submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the PA, NP, and/or CNS has furnished or is reasonably expected to furnish one or more of the specified psychotherapy or medication prescription to at least 20 patients within a 12 month period.

This provision will help to ensure compliance.

Comment: Some commenters stressed that network adequacy requirements should accurately reflect the actual availability of health care providers. These commenters emphasized that CMS should tailor its approach to address the unique barriers that underserved rural areas face in accessing behavioral health services. Some commenters suggested that including NPs, PAs, and CNSs is particularly important in rural areas where there is often a shortage of health care providers. Commenters noted that NPs are increasingly providing behavioral health services, with a significant percentage treating conditions like depression in their practice. Commenters supported the proposed changes to expand the definition of behavioral health providers through the Outpatient Behavioral Health network adequacy requirement since it will not only address the provider shortage, but also align with the goal of ensuring that MA enrollees have access to comprehensive and high-quality behavioral health care.

Response: We thank commenters for their support of our proposal to include certain provider types such as NPs, PAs, and CNSs as part of the Outpatient Behavioral Health network adequacy standard. Our network adequacy standards take into account the unique access challenges in rural areas. Network adequacy is assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations), this allows us to set our criteria to represent the geographic variations across the United States based on population size and density of each county.

Comment: We received numerous comments supporting our proposal to add Outpatient Behavioral Health specialty type to the list at § 422.116(d)(5), which would provide a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when the plan includes one or more telehealth providers that offer additional telehealth benefits as defined in § 422.135 in its contracted network. Commenters agreed that network access through telehealth benefits is critical, especially for enrollees in rural areas where traditional services may be less accessible.

A few commenters suggested that CMS should increase the telehealth credit from the proposed 10 percent up to 30 percent or that we increase the credit and make it applicable to all behavioral health network adequacy standards under § 422.116(d)(5). Other commenters expressed concerns regarding CMS's proposal to add Outpatient Behavioral Health to the list at § 422.116(d)(5). Commenters cautioned against an over-reliance on telehealth that may not provide the same level of care as in-person visits. These commenters emphasized the need for telehealth services to adhere to the same capacity and accessibility standards as in-person services, including the ability to accept new patients and deliver specified services promptly.

Response: Our decision to extend the telehealth credit for the new Outpatient Behavioral Health facility-specialty type is consistent with our established practice for MA organizations receiving the credit as part of a network adequacy evaluation. As we previously mentioned, Medicare Fee-For-Service (FFS) claims data indicated that telehealth was the second most common place of service for claims with a

primary behavioral health diagnosis in 2020.

The telehealth credit is designed to encourage the use of telehealth services but is not a replacement for in-person care. Per § 422.116(d)(5), the telehealth credit is available when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in the listed specialties. Consistent with § 422.135, MA plans that cover additional telehealth benefits must offer enrollees the option to choose their preferred mode of care delivery and to access the services in person. This requirement underlines our commitment to encouraging use of and access to telehealth without compromising the availability of in-person care. Providers who receive the telehealth credit are listed under § 422.116(d)(5) and currently include all outpatient behavioral health providers that are evaluated for network adequacy purposes.

We understand and appreciate the concerns raised about the potential over-reliance on telehealth services. We agree it is necessary for these services to meet the same standards of capacity and accessibility as in-person visits, including the acceptance of new patients and the timely delivery of specified services. We recognize the careful balance between expanding access through telehealth and maintaining the quality and immediacy of care. As we move forward, CMS will continue to monitor the effectiveness and impact of the telehealth credit on network adequacy, especially in the context of Outpatient Behavioral Health services. We remain open to considering adjustments to the telehealth credit percentage in future rulemaking based on evidence, stakeholder feedback, and the evolving landscape of telehealth services. Our goal is to ensure that our policies support the effective use of telehealth in enhancing access to care while maintaining high standards of care delivery for MA enrollees.

Comment: Commenters requested clarification from CMS on whether primary care practices that integrate behavioral health services, including those staffed by MFTs, MHCs, and addiction medicine physicians, fall under the ''Outpatient Behavioral Health'' category. Commenters expressed that this clarification is critical to accurately reflect network adequacy, especially since many MFTs work in medical offices that provide behavioral health services.

Response: We confirm that primary care practices that integrate behavioral health services are within the scope of the ''Outpatient Behavioral Health'' category provided that the practice includes providers of the type listed in § 422.116(b)(2)(xiv), such as MFTs and MHCs, and PAs, NPs, CNSs, and addiction medicine physicians who regularly furnish or will regularly furnish behavioral health counseling or therapy services. These services can be represented at the level of individual providers or as a facility, depending on their billing practices.

We are committed to conducting an in-depth evaluation of network adequacy, acknowledging the changing landscape of healthcare delivery where behavioral health services are becoming an integral part of primary care. To that end, CMS annually publishes a Provider Supply file (42 CFR 422.116(a)(4)(ii)) that lists available providers and facilities and their corresponding office locations and specialty types. MA organizations may use this as a resource to identify providers and facilities. However, given the dynamic nature of the market, MA organizations remain responsible for conducting validation of data used for network adequacy review purposes.

Comment: Some commenters raised concerns regarding the possibility of delays in the enrollment of MFTs and MHCs as Medicare providers, as these providers will be registering for the first time. Commenters suggested that CMS should closely monitor any potential backlogs of providers or delay implementation of this rule if such issues arise.

Response: We are monitoring any potential issues or backlogs with MFTs and MHCs enrolling as Medicare providers. We do not foresee any such barriers to new provider enrollments at this time, and therefore would not need to delay implementation of this rule.

Comment: Several commenters suggested that CMS should create a complete list of qualifications for MFTs and MHCs so that MA plans can properly determine and incorporate eligible providers.

Response: The qualifications for MFTs and MHCs are specified in section 1861(lll) of the Act. Specifically, MFT services are defined in section 1861(lll)(1) and the term MFT is defined in section 1861(lll)(2); MHC services are defined in section 1861(lll)(3) and the term MHC is defined in section 1861(lll)(4) of the Act. These definitions provide the necessary information for MA organizations to understand and comply with the requirement to cover Part B covered services, which now includes the services furnished by MFTs and MHCs as newly defined eligible providers. MA organizations are required to cover these services as defined in the Act and ensure that they are furnished by providers who meet the qualifications specified in section 1861(lll)(2) of the Act for MFTs and in section 1861(lll)(4) of the Act for MHCs. We also direct readers to the regulations at 42 CFR 410.53 and 410.54 for CMS regulations on Medicare-covered MFT and MHC services.

Comment: Commenters suggested policy adjustments to allow for more realistic and flexible standards for network adequacy in underserved rural areas. For example, a few commenters recommended that CMS introduce waivers or exceptions to address difficulties faced by plans in contracting with a diverse range of providers due to workforce shortages.

Response: We acknowledge the unique circumstances in rural areas. CMS already addresses these circumstances when setting network time and distance standards according to county type to account for the different level of access in existing patterns of care for populations in these areas. To further account for the specific landscape in a particular area, CMS's time and distance standards measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities (42 CFR 422.116(d)(1)(i)). In addition, we have established guidelines under 42 CFR 422.116(f), which were finalized in our June 2020 final rule, that outline the circumstances under which an MA plan may request an exception to the network adequacy criteria. These provisions are designed to provide flexibility while ensuring that beneficiaries have access to necessary healthcare services.

Comment: Commenters expressed that many behavioral health providers possess multiple professional credentials, enabling them to qualify for more than one behavioral health specialty category. Commenters recommended that CMS permit providers holding multiple credentials to be included in the new behavioral health specialty category and be counted within each applicable specialty.

Response: In our proposal, we indicated that MA organizations may not submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty to meet that network specialty requirement and then submit that same provider as an ''Outpatient Behavioral Health facility'' to meet this separate standard. 88 FR 78485. We explained that because Outpatient Behavioral Health is not a specialty on its own,

such as other specialty types like Primary Care Physicians or Cardiologists, but rather is an umbrella term for which several specialties can be used to meet the requirement, it is important to make this distinction. We acknowledge that there are other circumstances when providers may hold multiple credentials that enable them to be counted under more than one network adequacy standard. We clarify here that MA organizations are still allowed to submit these types of providers, for purposes of network adequacy evaluation, under each applicable category that meets the specialty type requirements as defined under statute and meet the requirements of the standard in § 422.116. Organizations are responsible for ensuring that the contracted providers meet state and federal licensing requirements as well as the organization's credentialing requirements for each specialty type.

Comment: A few commenters requested that CMS consider postponing the new Outpatient Behavioral Health network adequacy standard until 2026 in order to provide flexibility for provider certification and contracting discussions with the relevant provider types.

Response: Behavioral health services, including the OTP benefit, MFT and MHC services are covered under Traditional Medicare today, so MA plans should have a network in place that assures adequate access to those services when medically necessary for enrollees under section 1852(d) of the Act and § 422.112. Therefore, we expect that MA organizations are already conducting ongoing work related to provider contracting and evaluating prevailing patterns of health care delivery in their service areas. We anticipate issuing guidance on the specified behavioral health services that need to be regularly furnished by PAs, NPs, and CNSs, for them to be submitted under the Outpatient Behavioral Health facility-specialty type after release of this final rule so that MA organizations can determine how to include those providers in their HSD tables for CMS to evaluate the provider network. The applicability date of January 1, 2025, of this final rule, provides sufficient time for organizations to prepare to include these provider types for the formal network adequacy evaluations conducted by CMS under § 422.116 beginning in 2025.

Based on our review and consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions as proposed with modifications to outline the criteria MA organizations must use to determine when an NP, PA or CNS can be considered as part of a network to meet the Outpatient Behavioral Health network adequacy standard. To address concerns that NPs, PAs, and CNSs might lack the necessary skills, training, or expertise to effectively address the behavioral health needs of enrollees and that the absence of criteria for incorporating these provider types could result in networks where these providers may be listed in a provider directory without actively treating patients, '' we are finalizing provisions in § 422.116(b)(2)(xiv) to establish specific criteria that MA organizations must use to determine when an NP, PA or CNS can be considered part of a network to meet the Outpatient Behavioral Health network adequacy standard. MA organizations must independently verify that the provider has furnished or will furnish certain services to 20 patients within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data. For NPs, PAs, or CNSs new to independent practice, MA organizations must have a reasonable and supportable basis for concluding that the practitioner would meet the requirement in the next 12 months, including information related to psychiatry or addiction medicine specialized training, and that the provider listed as a psychiatry or addiction medicine NP, PA, or CNS on public-facing websites.

L. Improvements to Drug Management Programs (§§ 423.100 and 423.153)

Section 1860D–4(c)(5)(A) of the Act requires that Part D sponsors have a drug management program (DMP) for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), currently defined by CMS as opioids and benzodiazepines. CMS codified the framework for DMPs at § 423.153(f) in the April 16, 2018 final rule ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Programs, and the PACE Program'' (83 FR 16440), hereafter referred to as the April 2018 final rule.

Under current DMP policy, CMS identifies potential at-risk beneficiaries (PARBs) who meet the clinical guidelines described at § 423.153(f)(16), which CMS refers to as the minimum Overutilization Monitoring System (OMS) criteria. CMS, through the OMS, reports such beneficiaries to their Part D plans for case management under their DMP. There are also supplemental clinical guidelines, or supplemental OMS criteria, which Part D sponsors can apply themselves to identify additional PARBs. Under § 423.153(f)(2), sponsors are required to conduct case management for PARBs, which must include informing the beneficiary's prescribers of their potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary.

If the sponsor determines through case management that the enrollee is an at-risk beneficiary (ARB), after notifying the beneficiary in writing, the sponsor may limit their access to opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit, in accordance with the requirements at § 423.153(f)(3). CMS regulations at § 423.100 define exempted beneficiary, at-risk beneficiary, potential at-risk beneficiary, and frequently abused drug.

1. Definition of Exempted Beneficiary § 423.100

Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. At § 423.100 CMS defines an exempted beneficiary as an enrollee being treated for active cancer-related pain, or who has sickle-cell disease, resides in a long-term care facility, has elected to receive hospice care, or is receiving palliative or end-of-life care.

The OMS criteria finalized in the April 2018 final rule were developed to align with available information and guidelines, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016 CDC Guideline) issued in March 2016.[27] The current policy to exempt beneficiaries with cancer from DMPs was developed through feedback from interested parties and alignment with the 2016 CDC Guideline's active cancer treatment exclusion. Patients within the scope of

[27] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

the 2016 CDC Guideline included cancer survivors with chronic pain who have completed cancer treatment, were in clinical remission, and were under cancer surveillance only. The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain (2022 CDC Guideline) [28] expands and updates the 2016 CDC Guideline to provide evidence-based recommendations for prescribing opioid pain medication for acute, subacute, and chronic pain for outpatients aged ≥18 years, excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care.

In the interest of alignment with the 2022 CDC Guideline regarding applicability in individuals with cancer, we proposed to amend the regulatory definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain.'' With this proposal, we would expand the definition of exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

We solicited comments on this proposal.

Comment: Most commenters supported the proposal to expand the definition of exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. One commenter suggested that expanding the definition to cancer-related pain beyond beneficiaries undergoing active cancer treatment better encompasses the range of patients with cancer related circumstances who are in need of extended pain relief. Other commenters agreed that the proposed definition was aligned with the 2022 CDC Guideline regarding individuals with cancer or cancer-related pain treatment. Other commenters agreed that enrollees being treated for cancer-related pain require long-term pain management, commonly including opioid pain medications, and thus, should be exempted from DMPs that are intended to address potential opioid misuse. Another commenter wanted to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options. Another commenter agreed that many patients in cancer survivorship experiencing pain-related lasting effects of treatment or disease should be excluded from these exemptions.

Response: We thank the commenters for their support.

Comment: A commenter appreciated CMS's efforts to improve the definition of an ''exempted beneficiary'' but was concerned that the proposal was too broad and would inadvertently include individuals who are not experiencing cancer- or cancer treatment-related pain, but instead are experiencing pain and have a prior, unrelated cancer diagnosis. The commenter wanted to ensure clinicians involved in case management will be able to exercise their professional judgement in determining whether an opioid used for ''cancer-related pain'' is reasonable, particularly when the cancer has been resolved for several years and/or required minimal treatment. The commenter wanted to ensure that CMS does not change the OMS criteria based on this change in definition. The commenter also suggested that a member who meets the criteria for identification in the OMS should not be omitted based solely on a diagnosis code indicating a history of cancer or cancer-related pain.

Response: CMS disagrees that the proposal is too broad. Our analysis of beneficiary data estimates only a small increase in exempted beneficiaries as a result of the proposed updated definition, which we used to estimate burden in the proposed rule. Refer to section X. Collection of Information Requirements, ICRs Regarding to Improvements to Drug Management Programs in this final rule for additional details. Beneficiaries who meet the regulatory definition for exempted beneficiary must be exempted from the DMP despite meeting all other OMS criteria. CMS attempts to remove exempted beneficiaries from OMS reporting; however, we acknowledge that the data we have at the time of quarterly OMS reporting may not be complete. Part D sponsors must use data available to them or obtained through case management to identify exempted beneficiaries, including those who are reported by OMS or when the sponsor is reviewing cases and making its own determinations based on OMS criteria. Therefore, a Part D sponsor's DMP may identify a beneficiary who meets the OMS criteria and allow clinicians to perform case management until it is determined that the beneficiary is exempt and must be removed from the program. This proposal changes the definition of ''exempted beneficiary'' at § 423.100 and does not change the OMS criteria or clinical guidelines described at § 423.153(f)(16).

Comment: One commenter was concerned with identification of patients whose opioid use is appropriately linked to cancer-related pain but who are not otherwise receiving active treatment for some form of cancer. The commenter pointed out that while plans have access to clinical data on members, there is a need to conduct additional administrative and clinical reviews of patient records to properly exempt individuals meeting this new standard from participation in DMPs. The commenter also anticipated a slight increase in the number of individuals who will be exempted from DMPs due to cancer-related pain under the proposed definition and a transition period in which existing processes designed to identify ARBs evolve to match the broader exemption for cancer-related pain.

Response: We acknowledge that there will be a transition period for DMPs to adapt their processes for the proposed exemption. Part D sponsors may identify exempted beneficiaries before or during case management. We expect sponsors to diligently engage in case management, but there is no deadline for sponsors to complete it. We also recognize that every case is unique and that the time needed for case management will vary depending on many factors, such as the complexity of the case, and the promptness with which, and whether, prescribers respond to sponsors' outreach. While the approach to case management may vary based on the facts and circumstances of the case, the general goal of case management is to understand why the beneficiary meets the OMS criteria and whether a limitation on access to coverage for FADs is warranted for the safety of the beneficiary. Thus, Part D sponsors are expected to address all cases without unreasonable delay and to triage their review of the most concerning cases to the extent possible.

Comment: A commenter agreed with the proposed updates but recommended that CMS establish a clinical documentation code that reflects the new definition, as is the case today with ''active cancer-related pain.'' The commenter suggested that for accurate identification of exempted beneficiaries, Part D plans would need specific exclusion identifiers for the term ''cancer-related pain.'' The commenter also asked that CMS provide guidance allowing case management

[28] *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm.*

documentation to be sufficient for ''cancer-related pain'' in situations when there is no code submitted by a provider. Another commenter suggested that it would be extremely helpful if CMS could indicate in the detailed OMS report the reason why a member was identified for DMP review and, when this is based on a diagnosis, when the diagnosis was made. The commenter also stated that stand-alone Prescription Drug Plans (PDPs) have no access to medical encounter data or to the member's medical history and even Medicare Advantage Prescription Drug Plans (MA–PDs) lack visibility into events that pre-date a member's enrollment with the MA–PD.

Response: We will share all exemption codes used in the OMS reporting in the technical user guide, including any codes for cancer-related pain. Should there be no code for cancer-related pain available from a provider, plans should ensure that case management documentation is sufficiently clear to justify OMS case responses to CMS.

We will also consider how best to update future OMS reporting, including the level of detail reported for PARBs. As detailed in the OMS technical user guide available on the CMS Part D Overutilization website,[29] the quarterly OMS report to Part D sponsors currently provides a list of beneficiaries meeting the minimum OMS criteria during the measurement period and information including the criteria met (*i.e.,* based on level of opioid use from multiple prescribers/pharmacies (referred to as MIN1) or history of opioid-related overdose (referred to as MIN2)).

Comment: Another commenter agreed with the proposed updates to the definition of exempted beneficiary but requested further guidance on when and how to intervene earlier when it is unclear that a beneficiary is using drugs aberrantly, which may increase DMP case volume without achieving the program's goal. The commenter also requested that CMS publish any criteria under consideration for use.

Response: While Part D sponsors may not vary the OMS criteria to include more or fewer beneficiaries in their DMPs, they may apply the criteria more frequently than CMS currently does, which is quarterly. A sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt (including in their internal claims systems), whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external data source. As part of ongoing case management, CMS expects plan sponsors to have a process in place to regularly monitor such information for enrollees in their DMP, and to take appropriate action expeditiously, when they obtain new information. In the November 2023 proposed rule, CMS provided information on data analysis and solicited feedback on potentially using a machine-learning model to enhance the minimum or supplemental OMS criteria in the future. This Request for Information is addressed in section III.N. Improvements to Drug Management Programs, OMS Criteria Request for Feedback of this final rule.

Comment: Another commenter agreed with the proposed update but added that the CDC Guideline also refers to specialty guidelines as an evidence-based resource for pain management in certain populations. A commenter noted that the guidelines may be an additional useful resource for plans as this policy is updated and implemented. The commenter referred to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Adult Cancer Pain, NCCN Clinical Practice Guidelines in Oncology: Survivorship, and Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline for recommendations on pain management for patients with cancer and patients who have survived cancer and American Society of Hematology 2020 Guidelines for Sickle Cell Disease: Management of Acute and Chronic Pain.

Response: We thank the commenter for the feedback and agree that CMS should refer Part D sponsors to the guidelines for both cancer-related pain and sickle-cell disease. We remind Part D sponsors that while both cancer-related pain and sickle-cell disease diagnoses exempt Part D enrollees from DMPs and coverage limitations on FADs, Part D sponsors must still comply with other utilization management requirements in § 423.153 to continue to monitor the safe use of opioids.

After reviewing the comments received, we are finalizing the proposal to amend the regulatory definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain'' without modification.

2. Drug Management Program Notices: Timing and Exceptions § 423.153(f)(8)

As discussed above under section III.N. Improvements to Drug Management Programs of this final rule, sponsors must provide case management for any PARB that meets the OMS criteria to determine whether the individual is an ARB and whether to implement a limitation on their access to FADs. Under section 1860D–4(c)(5)(B)(i)(I) of the Act, a sponsor must send an initial and second notice to such beneficiary prior to imposing such limitation. In the April 2018 final rule (83 FR 16440), CMS adopted requirements for the initial and second notices at §§ 423.153(f)(5) and 423.153(f)(6). The initial notice must inform the beneficiary that they have been identified as a PARB and must include information outlined in § 423.153(f)(5)(ii). The second notice must inform the beneficiary that they have been identified as an ARB and of the limitations on the beneficiary's coverage of FADs, as specified in § 423.153(f)(6)(ii). In the event that, after sending an initial notice, a sponsor determines that a PARB is not an ARB, a second notice is not sent; instead, an alternate second notice is sent. Though not required by the Act, CMS codified a requirement at § 423.153(f)(7) to provide an alternate second notice for the purpose of informing the beneficiary that they are not an ARB and that no limitation on their coverage of FADs will be implemented under the DMP.

Section 1860D–4(c)(5)(B)(iv) of the Act establishes that sponsors must send a second notice on a date that is not less than 30 days after the initial notice. The 30 days allow sufficient time for the beneficiary to provide information relevant to the sponsor's determination, including their preferred prescribers and pharmacies. CMS codified at § 423.153(f)(8) the timing for providing both the second notice and alternate second notice. Currently, CMS requires sponsors to send either the second or alternate second notice on a date not less than 30 days from the date of the initial notice and not more than the earlier of the date the sponsor makes the determination or 60 days after the date of the initial notice.

We proposed to change the timeframe within which a sponsor must provide an alternate second notice to a beneficiary who is determined to be exempt from the DMP subsequent to receiving an initial notice. Specifically, we proposed to redesignate existing § 423.153(f)(8)(ii) as § 423.153(f)(8)(iii), and to revise the text at § 423.153(f)(8)(ii) to specify that, for such exempted beneficiaries, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if that occurs less than 30 days from the date of the initial notice. In other words, we proposed to remove the

[29] *https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/improving-drug-utilization-review-controls-part-d.*

requirement that sponsors wait at least 30 days from the date of the initial notice to send the alternate second notice to exempted beneficiaries.

Through program oversight, including audits of Part D sponsors, CMS has observed that initial notices are sometimes sent to Part D enrollees who meet the definition of an exempted beneficiary at § 423.100, often because the sponsor does not have the necessary information—for example, that the enrollee has a cancer diagnosis or is receiving palliative care or end-of-life care—at the time the sponsor sends the initial notice. However, this information may be provided later by the enrollee or their prescriber in response to the initial notice. In some cases, sponsors identify exemptions very quickly after issuing the initial notice, prior to 30 days elapsing. Under current CMS regulations, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP. Therefore, as stated in the preamble to the April 2018 final rule (83 FR 16455), a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt (whether that be via the beneficiary, their representative, the facility, a pharmacy, a prescriber, or an internal or external data source, including an internal claims system). CMS understands that sponsors may have already been sending alternate second notices after determining that a beneficiary is exempt, without waiting for 30 days to elapse. This proposed change would specify that sponsors must send such notices to exempted beneficiaries sooner than 30 days after the provision of the initial notice.

CMS reminds Part D sponsors that, during their review and during case management, they are expected to use all available information to identify whether a PARB is exempt in advance of sending an initial notice to protect these vulnerable beneficiaries from unnecessary burden, anxiety, and disruptions in medically necessary drug therapy. Thorough review of plan records and robust outreach efforts to prescribers during case management help to minimize the risk that an exempted beneficiary would receive an initial notice.

Sections 8.1 and 8.2.2 of the DMP guidance [30] state that if a sponsor learns that a beneficiary is exempt after sending an initial notice, the sponsor should inform the beneficiary that the initial notice is rescinded. If less than 30 days have passed since the initial notice, a sponsor should send a Part D Drug Management Program Retraction Notice for Exempted Beneficiaries. The model retraction notice addresses the required 30-day timing issue in the current regulation. As proposed, the Part D Drug Management Program Retraction Notice for Exempted Beneficiaries would no longer be used because sponsors would instead send the alternate second notice. We did not estimate any reduction of burden for sponsors no longer using the Retraction Notice. The Retraction Notice was implemented as a temporary solution for Part D sponsors to use for exempted beneficiaries in place of the alternate second notice, which had been accounted for in the latest version of CMS–10141 (OMB control number 0938–0964).

We note that sponsors may determine that a PARB is not an ARB prior to 30 days elapsing for reasons other than the beneficiary being exempt. However, we believe the existing 30-day requirement before a sponsor may send an alternate second notice in such situations is important to maintain because it allows the beneficiary and other prescribers enough time to provide the sponsor with information that may influence the sponsor's determination.

We received the following comments on this proposal and our responses follow.

Comment: We received several comments supporting our proposal to eliminate the requirement that sponsors wait 30 days to send an alternate second notice to a beneficiary determined to be exempt after receiving an initial notice. Commenters described the proposal as efficacious, reasonable, and aimed at protecting exempted beneficiaries from unnecessary burden, including interrupted treatments. No commenters opposed this proposal. One commenter expressed support for discontinuing use of the Part D DMP Retraction Notice for Exempted Beneficiaries, noting that the Retraction Notice would no longer be needed under this proposal.

Response: We thank the commenters for their support and are finalizing this provision as proposed.

We proposed an additional technical change related to the timeframe for providing second notices and alternate second notices. The current regulation at § 423.153(f)(8)(i) requires that a sponsor provide a second notice or alternate second notice not more than the earlier of the date the sponsor makes the relevant determination or 60 days after the date of the initial notice. It is critical that beneficiaries receive timely written notice about changes to their access to Part D drugs, as well as information about appeal rights, and the second notice and alternate second notices are tied to the date of the plan's determination. However, CMS understands that sponsors may not always be able to issue printed notices on the exact day they make a determination for a variety of reasons, such as they made the determination on a day when there is no United States Postal Service mail service, or later in the day after files have been sent to a print vendor. Specifically, we proposed to add at § 423.153(f)(8)(i)(A) a window of up to 3 days to allow for printing and mailing the second notice or alternate second notice. We noted in the proposed rule that this change would provide sponsors sufficient time to print and mail the notices while ensuring that beneficiaries receive timely information about DMP limitations. Sponsors must continue to issue these notices as soon as possible when a determination is made, and CMS does not expect that sponsors will routinely take the maximum amount of time.

We did not propose to change the requirement in § 423.153(f)(8)(i)(B) that the second notice or alternate second notice must be provided no later than 60 days from the date of the initial notice. This is because sponsors have ample time to account in advance for the days needed to print and mail these notices.

We received the following comments on this proposal and our responses follow.

Comment: We received several comments on this proposal. Commenters were supportive of adding a window of time between making a determination and providing the second notice or alternate second notice; no commenters were opposed. Most of these commenters noted the importance of notifying beneficiaries as soon as practicable about DMP determinations.

Response: CMS thanks the commenters for their support.

Comment: Several of the commenters that generally supported this proposal opined that CMS should allow more than 3 days for sponsors to provide the second notice or alternate second notice following a determination, and offered specific recommendations, including allowing up to 4 days, 5 business days, or 7 calendar days. One commenter stated that weekends and holidays would make the proposed 3-day window almost impossible to meet. Another commenter opined that sponsors should not be held to the same timeframe that applies to written notice of a Part D coverage determination

[30] *https://www.cms.gov/files/zip/cy-2023-part-d-dmp-guidance-april-20-2023.zip.*

because of the impracticality of verbally conveying the information in a DMP notice prior to mailing the written notice. The commenter instead recommended that the timing align with the 7-day window that applies to other current requirements, including certain DMP data disclosure requirements. One commenter appeared to have misunderstood the existing timeframes for providing the second notice and alternate second notice.

Response: We thank the commenters for their feedback but disagree with their recommendations to allow more than 3 days between making the determination and providing the notice. These notices contain important information concerning a beneficiary's prescription drug access and must not be unnecessarily delayed. As described above and in the November 2023 proposed rule, there is precedent for establishing a 3-day window for sponsors to provide a written notice for coverage determinations under §§ 423.568(d) and (f) and 423.572(b). CMS recognizes that the DMP notices do not follow initial verbal notification, but that makes timely written notification even more important for these cases. Additionally, sponsors already have established processes for providing written notices within a 3-day timeframe, and these processes can be leveraged for sending DMP notices.

Regarding the data disclosure provision at § 423.153(f)(15)(ii)(D) that requires sponsors to update DMP information in MARx as soon as possible but no later than 7 days from the date the sponsor provides an initial notice or second notice to a PARB or ARB or terminates a DMP limitation, it is important to note that this requirement is unrelated to beneficiary notification and thus not as urgent. The purpose of the data disclosure is not comparable to the purpose of sending beneficiary notices regarding a restriction on their access to Part D drugs; therefore, it is not an appropriate benchmark to use to establish this timeframe. CMS does not expect plans to routinely take the maximum amount of time possible and reminds sponsors that the maximum 60-day timeframe from the date of the initial notice is unchanged under our proposal. For example, if a determination is made on day 60, the second notice or alternate second notice must be provided on the same day.

Currently, under § 423.153(f)(8)(i), Part D sponsors must provide the second notice or the alternate second notice on the date of the determination, with no additional window of time for providing (*i.e.,* printing and mailing) the written notice. As such, this change extends from 0 days to up to 3 days the time sponsors have to provide a notice after making a determination. After consideration of the comments received and existing Part D beneficiary notice requirements, CMS believes this change allows sponsors sufficient time to print and mail the notices while ensuring that beneficiaries receive timely information about their DMP limitations.

Comment: Some commenters requested clarification on how CMS will calculate the 3-day window for providing the alternate second notice and second notice and whether the provision refers to calendar or business days. One commenter asked whether CMS intends for plans to ensure the DMP notices are mailed within 3 days of the determination, or whether CMS intends for the beneficiary to receive the notice within 3 days of the determination.

Response: CMS intends that a sponsor will have issued (*i.e.,* printed and mailed, or sent electronically if the beneficiary has indicated such a preference) the second notice or alternate second notice within 3 days of making the relevant determination. We do not require sponsors to send these notices in a manner that tracks receipt by the beneficiary and consequently would be unable to enforce such a timeframe. We further clarify that this proposal refers to calendar days, consistent with the other DMP notice requirements specified at § 423.153(f)(8) and various beneficiary notice requirements throughout Part 423, Subpart M. CMS will update the 2025 DMP guidance to provide these clarifications as they relate broadly to the DMP beneficiary notice requirements.

After consideration of the comments received, we are finalizing the regulation text at §§ 423.153(f)(8)(i)(A) and 423.153(f)(8)(ii) as proposed.

3. OMS Criteria Request for Feedback

CMS regulations at § 423.153(f)(16) specify that CMS and Part D sponsors identify PARBs and ARBs using clinical guidelines that are developed with stakeholder consultation, derived from expert opinion backed by analysis of Medicare data, and include a program size estimate. In addition, the clinical guidelines (also referred to as the ''OMS criteria'') are based on the acquisition of FADs from multiple prescribers, multiple pharmacies, the level of FADs used, or any combination of these factors, or a history of opioid-related overdose.

PARBs are the Part D beneficiaries who CMS believes are potentially at the highest risk of opioid-related adverse events or overdose. The current minimum OMS criteria [31] identifies PARBs who (1) use opioids with an average daily morphine milligram equivalents (MME) of greater or equal to 90 mg for any duration during the most recent six months, who have received opioids from 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies, *or* from 5 or more opioid prescribers regardless of the number of dispensing pharmacies (also referred to as ''MIN1'' minimum OMS criteria), or (2) have a history of opioid-related overdose, with a medical claim with a primary diagnosis of opioid-related overdose within the most recent 12 months and a Part D opioid prescription (not including Medication for Opioid Use Disorder [32] (MOUD)) within the most recent 6 months (also referred to as ''MIN2'' minimum OMS criteria). Sponsors may use the current supplemental OMS criteria to address plan members who are receiving opioids from a large number of prescribers or pharmacies, but who do not meet a particular MME threshold. These are (1) use of opioids (regardless of average daily MME) during the most recent 6 months; AND (2) 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies.

In 2019, CMS assigned the Health Federally Funded Research and Development Center (FFRDC) to develop evidence-based recommendations for improving the OMS criteria for the future. The Health FFRDC conducted a literature review, facilitated a Technical Expert Panel (TEP), and performed data analyses. All three activities served as inputs into the evidence-based recommendations. The Health FFRDC recommended that the results of the literature review and data analysis support the continued inclusion of average MME, number of opioid dispensing pharmacies, and number of opioids prescribers as indicators for PARBs. In addition, they recommended that further data analysis would be necessary to determine which additional criteria would be appropriate to potentially adopt. CMS conducted subsequent literature reviews and analysis.

In recent years, there has been a marked decrease in Part D prescription opioid overutilization, but opioid-related overdose deaths continue to be

[31] April 20, 2023 HPMS memorandum, CORRECTION—Contact Year 2023 Drug Management Program Guidance available at: *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxutilization.*

[32] Referred to as medication-assisted treatment (MAT) in past guidance.

a growing problem throughout the United States.[33] While the CDC found synthetic opioids (other than methadone) to be the main driver of opioid overdose deaths, accounting for 82 percent of all opioid-involved deaths in 2020,[34] we must remain vigilant regarding the risks of prescription opioids including misuse, opioid use disorder (OUD), overdoses, and death. CMS tracks prevalence rates for Part D beneficiaries with an OUD [35] diagnosis and beneficiaries with an opioid poisoning (overdose). While overall opioid-related overdose prevalence rates among Part D enrollees have declined over the period from contract year 2017 through 2021 at about 6.5 percent per annum, overall opioid-related overdose prevalence rates increased by 1.0 percent between 2020 and 2021. Furthermore, about 1.6 percent of all Part D enrollees had a provider diagnosed OUD in Contract Year 2021, and the OUD prevalence rate has grown by 3.2 percent per annum since contract year 2017.

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[36] CMS finalized regulations to implement section 2004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act to include beneficiaries with a history of opioid-related overdose as PARBs in DMPs. While the implementation of the SUPPORT ACT enables identification of beneficiaries with a history of opioid-related overdose and continues to identify PARBs who receive high levels of opioids through multiple providers who may be more likely to misuse prescription opioids,[37] CMS is working on alternative methods to identify beneficiaries potentially at risk before their risk level is diagnosed as an OUD or the person experiences an opioid-related overdose.

A recently published article that evaluated the use of machine learning algorithms for predicting opioid overdose risk among Medicare beneficiaries taking at least one opioid prescription concluded that the machine learning algorithms appear to perform well for risk prediction and stratification of opioid overdose especially in identifying low-risk groups having minimal risk of overdose.[38] Machine learning is a method of data analysis that automates analytical model building, based on the idea that systems can learn from data, identify patterns and make decisions with minimal human intervention.

While we did not propose changes to the clinical guidelines or OMS criteria in the November 2023 proposed rule, we provided information on our data analysis to date and welcome feedback for future changes. Using predictor variables identified through the literature reviews, CMS performed a data analysis to determine the top risk factors for Part D enrollees at high-risk for one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D enrollees with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD. We anticipated no additional sponsor burden since we did not propose regulatory changes and solicited feedback.

In the analysis, we utilized Medicare data and traditional logistic regression as well as machine learning models like Random Forest, Least Absolute Shrinkage and Selection Operator (LASSO), and Extreme Gradient Boosting (XGBoost) [39] Cross Validation (CV) to examine and evaluate performance in predicting risk of opioid overdose and OUD. The models were compared based on the following criteria: Area Under the Curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and number needed to examine (NNE). An XGBoost model with CV performed best according to the specified criteria and was selected as the model of choice for predicting a beneficiary with a new opioid overdose or OUD diagnosis.

The model population included 6,756,152 Medicare beneficiaries contemporaneously enrolled in Part D and Parts A, B, or C during the period from January to June 2019, who were prescribed at least one non-MOUD prescription opioid during the measurement period and did not have a DMP exemption (that is, cancer, sickle cell disease, hospice, LTC facility resident, palliative care, or end-of-life care). We excluded beneficiaries with a prior opioid-related overdose or an OUD diagnosis in the year prior to the prediction period. The training dataset used to build the model consisted of a random 75 percent sample of the study population (5,067,114). The remaining 25 percent of the population (1,689,038) was used for validating the prediction performance of the model. The measurement period to obtain information for the predictor variables (for example, opioid use patterns, demographics, comorbidities, etc.) was from January 1 to June 30, 2019, and the prediction period we used to identify beneficiaries with a new opioid overdose event or new OUD diagnosis was from July 1 to December 31, 2019.

The following risk factors [40] were incorporated into the XGBoost model:

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[33] Spencer, Merianne R. et al. (2022). Drug Overdose Deaths in the United States, 2001–2021. (457).

[34] *https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html.*

[35] CMS used a modified version of the Chronic Condition Warehouse (CCW) definition that excludes undiagnosed OUD beneficiaries such as those with an opioid OD event and also limits analysis to the particular measurement period instead of the prior two years.

[36] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the U.S. Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

[37] Over 30,000 Part D enrollees met the minimum OMS criteria and were reported to sponsors through OMS reports in 2022 (18 percent met the level of opioid use though multiple provider criteria, and 82 percent met the history of history of opioid-related overdose criteria).

[38] Lo-Ciganic WH, Huang JL, Zhang HH, Weiss JC, Wu Y, Kwoh CK, Donohue JM, Cochran G, Gordon AJ, Malone DC, Kuza CC, Gellad WF. Evaluation of Machine-Learning Algorithms for Predicting Opioid Overdose Risk Among Medicare Beneficiaries With Opioid Prescriptions. JAMA Netw Open. 2019 Mar 1;2(3):e190968. doi: 10.1001/jamanetwork open.2019.0968. Erratum in: JAMA Netw Open. 2019 Jul 3;2(7):e197610. PMID: 30901048; PMCID: PMC6583312.

[39] Extreme Gradient Boosting (XGBoost) model—data mining technique that is similar to Random Forest that combines multiple decision trees into a single strong prediction model, but it differs in doing so in an iterative manner by building one tree at a time and optimizing a differentiable loss function.

[40] Multicollinearity tests were undertaken in order to ensure that there was no collinearity among the explanatory variables used in the model.

TABLE CN-1: Risk factors used for the XGBOOST MODEL

Risk Factor Flag	Description
Age	Beneficiary age in years
Sex	Female or Male sex
Race	White, Black, Asian, Hispanic, Native American, Other or Unknown race/ethnicity
LIS	Beneficiary low-income subsidy status
Dual	Beneficiary dual-eligibility status
Current Medicare Entitlement	Beneficiary current Medicare entitlement: ESRD (1) / non-ESRD (2)
MME	Average daily morphine milligram equivalents (MME)
Number of Opioid Pharmacies	Number of different pharmacies with an opioid prescription drug event (PDE) claim
Number of Opioid Prescribers	Number of different opioid prescribers
Number of Short-Acting Opioid Fills	Number of short-acting opioid PDEs
Number of Long-Acting Opioid Fills	Number of long-acting opioid PDEs
Number of Different Prescription Opioids	Number of different opioids prescribed (GPI-14[41])
Number of MOUD Days	Number of Medication-Assisted Treatment (MOUD) days
Hepatitis	Hepatitis diagnosis
Cervical nerve injury	Cervical nerve injury diagnosis
Lumbar nerve injury	Lumbar nerve injury diagnosis
Thoracic nerve injury	Thoracic nerve injury diagnosis
Neuropathy	Neuropathy diagnosis
Other chronic pain	Other chronic pain diagnosis
Number of Mental Health Conditions	Number of mental health conditions (ADHD, anxiety, bipolar, depression, PTSD, personality disorder, schizophrenia) diagnosed
Number of Substance Use Disorders	Number of substance use disorders (alcohol, cannabis, hallucinogen, inhalant, non-psychoactive, psychoactive, sedative, stimulant) diagnosed

[41] The Generic Product Identifier (GPI) designates any or all of a drug's group, class, sub-class, name, dosage form, and strength.

Risk Factor Flag	Description
	hallucinogen, inhalant, non-psychoactive, psychoactive, sedative, stimulant) diagnosed
Antianxiety Drug Fill	PDE claim for antianxiety drug
Antipsychotic Drug Fill	PDE claim for antipsychotic drug
Anticonvulsant Drug Fill	PDE claim for anticonvulsant drug
Concurrent use of opioid and benzodiazepine (1 or more days)	Concurrent PDE for opioid and benzodiazepine (1+ day overlap)
Concurrent use of opioid and benzodiazepine (30 or more days)	Concurrent PDE for opioid and benzodiazepine (30+ day overlap)
Codeine Fill	PDE opioid claim for codeine (GPI-10)
Fentanyl Fill	PDE opioid claim for fentanyl (GPI-10)
Methadone Fill	PDE opioid claim for methadone (GPI-10)
Morphine Fill	PDE opioid claim for morphine (GPI-10)
Oxycodone Fill	PDE opioid claim for oxycodone (GPI-10)
Oxymorphone Fill	PDE opioid claim for oxymorphone (GPI-10)
Tramadol Fill	PDE opioid claim for tramadol (GPI-10)
Hydrocodone Fill	PDE opioid claim for hydrocodone (GPI-10)
Hydromorphone Fill	PDE opioid claim for hydromorphone (GPI-10)
Other Opioid Fill	PDE opioid claim for other opioid (GPI-10)

We evaluated the performance of the model using the confusion matrix generated by applying the prediction model to the validation dataset to calculate various metrics.

TABLE CN-2: Confusion Matrix for the XGBoost Model

Actual New OUD or Opioid-Related Overdose Diagnosis:	Predicted New OUD or Opioid-Related Overdose Diagnosis: No	Predicted New OUD or Opioid-Related Overdose Diagnosis: Yes	Total
No	1,154,395	513,551	1,667,946
Yes	3,920	17,172	21,092
Total	1,158,315	530,732	1,689,038

TABLE CN-3: Performance Metrics for the XGBoost Model

Criteria	Result
AUC	0.8253
Sensitivity	81.41 Percent
Specificity	69.21 Percent
PPV	3.24 Percent
NPV	99.66 Percent
NNE	31
Probability Threshold	0.474

The top 15 risk factors that were highly associated with a new OUD or opioid-related overdose diagnosis were:

TABLE CN-4: Top 15 Risk Factors

Rank	Risk Factor Variable	Gain
1	Number of Short-Acting Opioid Fills	0.3853
2	MME*	0.1256
3	Age	0.0882
4	Number of Long-Acting Opioid Fills	0.0729
5	Number of Mental Health Conditions	0.0539
6	Number of Substance Use Disorders	0.0298
7	Anticonvulsant Drug Fill	0.0294
8	Number of Different Prescription Opioids	0.0234
9	Oxycodone Fill	0.0230
10	Other Opioid Fill	0.0227
11	Dual	0.0200
12	Number of Opioid Prescribers*	0.0148
13	Concurrent use of opioid and benzodiazepine (30 or more days)	0.0134
14	Morphine Fill	0.0112
15	LIS	0.0102

*Part of current minimum OMS criteria.

The number of short-acting prescription opioid fills and the average daily MME were found to contribute most to XGBoost model predictions of a new OUD or opioid-related overdose diagnosis. Risk was present across a range of MME levels and increased with higher MME levels. The risk of developing a new OUD or opioid-related overdose diagnosis also increased with the number of diagnosed mental health or substance use disorders. Utilization of opioids with other high-risk medications like anticonvulsants, benzodiazepines, anti-psychotics, and anti-anxiety medications were positively associated with higher risk. Also, utilization of opioids like oxycodone and morphine were positively associated with higher risk, while utilization of codeine, tramadol, and opioids in the other category were positively associated with lower risk.

Lastly, we applied our finalized model to data from October 1, 2021 through March 31, 2022 to predict future new opioid-related overdose events and OUD diagnoses during the period from April 1, 2022 to September 30, 2022 to understand program size estimates and NNE values.

TABLE CN-5: Risk Probability Thresholds and Performance Metrics

Risk Probability Threshold	Number of Beneficiaries with Predicted New OUD or Opioid-Related Overdose Diagnosis	Number of True Positives*	PPV (Percent)	NNE
Top 1 percent**(Validation Data)	16,862	1,860	11.01	9
Top 1 percent	62,571	5,445	8.70	11
Top 50,000	50,000	4,562	9.12	11
Top 40,000	40,000	3,792	9.48	11
Top 30,000	30,000	2,996	9.99	10
Top 20,000	20,000	2,168	10.84	9
Top 10,000	10,000	1,219	12.19	8
Top 5,000	5,000	679	13.58	7
Top 1,000	1,000	150	15.00	7

*True Positives are beneficiaries that were categorized into the given risk probability threshold group based on data from the October 1, 2021 to March 31, 2022 measurement period, then were subsequently found to have experienced a new opioid OD/OUD during the April 1, 2022 to September 30, 2022 prediction period.
**Validation data: random 25 percent sample of total population: January 1, 2019 to June 30, 2019 measurement period, and July 1, 2019 to December 31, 2019 prediction period.

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Between 9 percent and 15 percent of the beneficiaries with a predicted new opioid-related overdose/OUD actually experienced a new overdose or OUD diagnosis during the evaluation period (April 1, 2022, through September 30, 2022) depending on the Risk Probability Threshold. The Top 1 percent threshold (n = 62,571) reported the lowest precision score, while the Top 1,000 threshold showed the highest precision. Among those who had a new opioid-related overdose/OUD in the evaluation period, about 92 percent developed a new OUD; the proportion with a new opioid overdose increased from 10 percent to 17 percent as the risk probability threshold increased from the Top 1 percent to the Top 1,000; and, as the risk probability threshold increased, about 2 percent to 8 percent had both a new opioid overdose and were identified as having a newly diagnosed OUD. Among the different Risk Probability Thresholds, between 93 to 98 percent of the correctly predicted new overdoses/OUDs do not meet the current OMS criteria. The percentage that meets the current OMS criteria decreases as the Risk Probability Threshold becomes more restrictive. Thus, our analysis shows that there is very little overlap between the population identified through this model and beneficiaries already identified through the OMS.[42] Furthermore, our analysis confirms that machine learning models can analyze large datasets and identify complex patterns that are not easily discernible by current non-statistical approaches. This makes them a powerful tool for identifying new opioid-related overdose or OUD risk and capturing an additional population of potential at-risk beneficiaries who have not been identified through our current OMS criteria.

In the November 2023 proposed rule, we discussed that CMS next plans to assess risk in the model, validate the stability of the model as new data become available, and develop guidelines on how to feasibly implement the model into the existing DMP and OMS processes. We solicited feedback on the following:

- Potentially using such a model to enhance the minimum or supplemental OMS criteria in the future (either in addition to the current criteria or as a replacement).
- How to avoid the stigma and/or misapplication of identification of a PARB at high risk for a new opioid-related overdose or OUD using the variables in the model.
- Implementation considerations, such as effectively conducting case management, as described in 423.153(f)(2), with prescribers of PARBs identified by the model; opportunities to promote MOUD, co-prescribing of naloxone, or care coordination; or potential unintended consequences for access to needed medications.
- Other factors to consider.

Comment: Commenters supported our machine learning model approach or further testing. Several commenters encouraged CMS to provide a demographic breakdown or the fairness analysis used to evaluate the model. Several commenters suggested that CMS use clearly defined risk factors that foster case management, ensure correctness of the risk factors used, or focus on distinguishing factors to identify at-risk beneficiaries and to minimize misapplication of the criteria for beneficiaries with low risk of overdose or OUD. One commenter recommended methods to better identify overdose risk such as removing beneficiaries who do not show continuous use of opioids after an overdose event and shortening look back windows.

Response: We thank the commenters for their support of our machine learning model approach and thoughtful input. CMS will consider the feedback, and we will proceed with further testing to improve the model and risk factors.

[42] CMS also notes that historically, only about 1.6 percent of the beneficiaries meeting the history of opioid-related overdose (MIN2) OMS criteria also meet the (MIN1) minimum OMS criteria.

The model focused on Part D beneficiaries at high-risk of one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D beneficiaries with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD. CMS also excluded beneficiaries with a prior opioid-related overdose or an OUD diagnosis in the year prior to the prediction period. Also, we did include demographic factors in the initial model and a few of the factors were highly associated with a new OUD or opioid-related overdose diagnosis as described above and in the November 2023 proposed rule. We will look for opportunities to provide additional details or output from the analysis after we conduct more testing.

Comment: Some commenters recommended that CMS assess whether any new criteria resulting from the use of such model could unintentionally lead providers to be less likely to diagnose someone with OUD, as that, in turn, would decrease access to MOUD.

Response: We will evaluate unintentional consequences of using updated criteria that may affect the likelihood of diagnosing beneficiaries with OUD. We encourage sponsors and prescribers to promote co-prescribing of naloxone, MOUD, or other treatment referrals through the DMP case management process.

Comment: Some commenters requested sufficient lead time and proper communication language be in place before CMS implements any changes.

Response: We did not propose changes to the clinical guidelines or OMS criteria in the November 2023 proposed rule. Changes would be proposed through a future notice of proposed rulemaking with sufficient lead time and guidance, if finalized.

M. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (CTM) (42 CFR 417.472(l), 422.125, 423.129, and 460.119)

CMS maintains the CTM in the Health Plan Management System (HPMS) as the central repository for complaints received by CMS from various sources, including, but not limited to the Medicare Ombudsman, CMS contractors, 1–800–MEDICARE, and CMS websites. The CTM was developed in 2006 and is the system used to comply with the requirement of section 3311 of the Affordable Care Act for the Secretary to develop and maintain a system for tracking complaints about MA and Part D plans received by CMS, CMS contractors, the Medicare Ombudsman, and others. Complaints from beneficiaries, providers, and their representatives regarding their Medicare Advantage (MA) organizations, Cost plans, Programs of All-inclusive Care for the Elderly (PACE) organizations, and Part D sponsors are recorded in the CTM and assigned to the appropriate MA organization (MAO), Cost plan, PACE organization, and Part D sponsor if CMS determines the plan, organization, or sponsor is responsible for resolving the complaint. Unless otherwise noted, ''plans'' applies to MAOs, Part D sponsors, Cost plans, and PACE organizations for purposes of this section.

We proposed to codify existing guidance for the timeliness of complaint resolution by plans in the CTM. Currently, §§ 422.504(a)(15) and 423.505(b)(22) require MAOs and Part D sponsors to address and resolve complaints received by CMS against the MAO and Part D sponsor through the CTM; we proposed to codify the expectation in guidance that Cost plans and PACE organizations also address and resolve complaints in the CTM. We proposed to codify the existing priority levels for complaints based on how quickly a beneficiary needs to access care or services and to codify a new requirement for plans to make first contact with individuals filing non-immediate need complaints within 3 calendar days. This timeframe will not apply to immediate need complaints because those complaints need to be resolved within two calendar days.

CMS codified the requirement for MAOs and Part D sponsors to address and resolve complaints in the CTM at §§ 422.504(a)(15) and 423.505(b)(22) in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (76 FR 21431), which appeared in the April 15, 2011 **Federal Register** (hereafter referred to as the ''April 2011 final rule''). As described in the April 2011 final rule, the regulation requires that MAOs and Part D sponsors provide a summary of the resolution in the CTM when a complaint is resolved. (76 FR 21470)

As Part D sponsors, Cost plans and PACE organizations that offer Part D coverage have been required to comply with § 423.505(b)(22). We proposed to add language to §§ 417.472(l) and 460.119 to codify in the Cost plan regulations and PACE regulations, respectively, the requirement that Cost plans and PACE organizations address and resolve complaints in the CTM. This proposed new requirement will apply to all complaints in the CTM for Cost plans and PACE organizations, not just complaints about Part D.

In addition, CMS has issued guidance describing our expectations for how complaints should be handled. In the Complaints Tracking Module Plan Standard Operational Procedures (CTM SOP), the most recent version of which was released on May 10, 2019, via HPMS memo,[43] CMS provides detailed procedures for plans to use when accessing and using the CTM to resolve complaints. This includes describing the criteria CMS uses in designating certain complaints as ''immediate need'' or ''urgent'' (all other complaints are categorized ''No Issue Level'' in the CTM), setting forth our expectation that plans should review all complaints at intake, and documentation requirements for entering complaint resolutions in the CTM. The CTM SOP defines an ''immediate need complaint'' for MAOs, Cost plans, and PACE organizations as ''a complaint where a beneficiary has no access to care and an immediate need exists.'' For Part D sponsors, ''an immediate need complaint is defined as a complaint that is related to a beneficiary's need for medication where the beneficiary has two or less days of medication remaining.'' The CTM SOP defines an ''urgent complaint'' for MAOs, Cost plans, and PACE organizations as a complaint that ''involves a situation where the beneficiary has no access to care, but no immediate need exists.'' For Part D sponsors, ''an urgent complaint is defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 3 to 14 days of medication left.''

In Chapter 7, section 70.1 of the Prescription Drug Benefit Manual, ''Medication Therapy Management and Quality Improvement Program,'' [44] CMS requires Part D sponsors to resolve any ''immediate need'' complaints within two (2) calendar days of receipt into the CTM and any ''urgent'' complaints within seven (7) calendar days of receipt into the CTM. Chapter 7, section 70.1 also sets forth CMS's expectation that Part D sponsors promptly review CTM complaints and notify the enrollee of the plan's action as expeditiously as the case requires based on the enrollee's health status.

[43] Available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ctm%20plan%20sop%20eff053019.pdf.*

[44] Available at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf.*

Requirements for resolution of complaints received in the CTM do not override requirements related to the handling of appeals and grievances set forth in 42 CFR part 422 subpart M (which apply to cost plans as well as MAOs per § 417.600), Part 423 subpart M, for Part D sponsors, and §§ 460.120–460.124 for PACE organizations. Rather, CTM requirements supplement the appeals and grievance requirements by specifying how organizations must handle complaints received by CMS in the CTM and passed along to the plan. The requirement for organizations to enter information on the resolution of complaints in the CTM within specified time periods allows CMS to track and ensure accountability for complaints CMS itself received, either directly from beneficiaries or via entries in the CTM from the Medicare ombudsman, CMS contractors, or others. A beneficiary who filed a complaint directly with CMS may later contact CMS to find out the status of the complaint and the plan's use of the system will allow CMS to answer the beneficiaries inquires more expeditiously. In order to comply with the applicable regulations, plans must handle any CTM complaint that is also an appeal or grievance within the meaning of the regulation in such a way that complies with the notice, timeliness, procedural, and other requirements of the regulations governing appeals and grievances.

We proposed to codify the timeliness requirements for MAOs and Part D plans at new §§ 422.125 and 423.129, both titled ''Resolution of Complaints in Complaints Tracking Module.'' We proposed to codify these requirements for Cost plans and PACE organizations at §§ 417.472(l) and 460.119 by adopting §§ 422.504(a)(15) and 422.125 by reference into the requirements for Cost plans and PACE organizations, respectively.

Specifically, we proposed to codify at §§ 422.125(a) and 423.129(a) the definitions of ''immediate need'' and ''urgent'' complaints in substantially the same way as they are currently defined in guidance for MA and Part D-related complaints. However, we proposed to specify that immediate need and urgent complaints for MA plans (as well as Cost plans, and PACE) also include situations where a beneficiary has access to enough of a drug or supply to last fewer than 2 days or from 3 to 14 days, respectively, as part of the definition that these complaints are about situations that prevent the beneficiary from accessing care or a service. This proposed change recognizes that some complaints to an MAO (or Cost plan or PACE organization) may overlap with Part D access, such as when a beneficiary reports a problem with their enrollment in an MA–PD plan that is blocking access to Part D coverage. The change also recognizes that non-Part D MA, Cost plan, and PACE complaints relate not just to access to physician services but to drugs and supplies that may be covered by the MA plan, Cost plan, or PACE organization's non-Part D benefit (for example, Part B drugs or diabetic test strips covered under the medical benefit of an MA plan). Further, MA plans, Cost plans, and PACE also cover Part B drugs.

We also proposed to codify at §§ 422.125(b) and 423.129(b) the current timeframes reflected in section 70.2 of Chapter 7 of the Prescription Drug Benefit Manual for resolving immediate need and urgent complaints. A two (2) calendar day deadline for resolving plan-related immediate need complaints is both consistent with current practice by plans and logically follows from the definition of an ''immediate need'' complaint. By its nature, an immediate need complaint requires swift action. Because we define immediate need, in part, as a situation where a beneficiary has access to two or fewer days' worth of a drug or supply they need, a timeline greater than two calendar days for resolving a complaint would represent an unacceptable risk to beneficiaries.

Similarly, a 7 calendar day deadline for ''urgent'' complaints reflects the importance of not delaying resolution of a situation that is preventing access to care or services a beneficiary needs. Because we define ''urgent'' in part as a situation where a beneficiary has 3 to 14 days' worth of a drug or supply they need, allowing more than a week to elapse before resolving the complaint will put beneficiaries at unacceptable risk of not receiving replacement drugs or supplies timely.

For all other Part D and non-Part D complaints in the CTM, we proposed requiring resolution within 30 days of receipt. This is consistent with current practice and the guidance in section 70.2 of Chapter 7 of the Prescription Drug Benefit Manual, and we believe will prevent complaints from lingering for months without resolution in the CTM. Further, a 30-day timeframe for resolving complaints in the CTM aligns with the 30-day period provided in §§ 422.564(e) and 423.564(e) for resolution of grievances. Although those regulations permit an extension of up to 14 days for resolving the grievance if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee, we do not believe that including the authority to extend the deadline to resolve complaints in the CTM is appropriate because complaints received into the CTM are often the result of failed attempts to resolve issues directly with the plan. Allowing plans to further extend the time to resolve the complaint only allows further delays in addressing beneficiary concerns. Moreover, recent evidence indicates that the vast majority of non-immediate need or urgent complaints are resolved within 30 days—98 percent of such complaints were resolved by plans within 30 days in 2022.

All timeframes for resolution will continue to be measured from the date a complaint is assigned to a plan in the CTM, rather than the date the plan retrieves the complaint from the CTM. This is consistent with current guidance and practice. Measuring the timeframe in this manner is the best way to protect beneficiaries from delayed resolution of complaints and encourages organizations to continue retrieving CTM complaints in a timely manner so that they have sufficient time to resolve complaints.

We do not anticipate that plans will have difficulty meeting these timeframes. The vast majority of complaints are currently resolved in the timelines specified for the priority level of the complaint. For example, in 2022, plans resolved 97 percent of complaints within the required time frames for the level of complaint. Plans resolved 94 percent of immediate need complaints within two (2) calendar days, 97 percent of urgent complaints within seven (7) calendar days, and 98 percent of complaints with no issue level designated within thirty (30) calendar days. Codifying the timeframes as proposed merely formalizes CMS's current expectations and the level of responsiveness currently practiced by plans.

We also proposed to create a new requirement for plans to contact individuals filing non-immediate need complaints. At §§ 422.125(c) and 423.129(c), we proposed to require plans to contact the individual filing a complaint within three (3) calendar days of the complaint being assigned to a plan. While current guidance generally includes the expectation that organizations inform individuals of the progress of their complaint, CMS has never specified a timeframe for reaching out to a complainant. CMS has observed that, particularly for complaints that are not assigned a priority level, plans sometimes wait until the timeframe for resolution has almost elapsed to contact the complainant. Because the timeframe

for resolving uncategorized complaints is 30 days, an individual who files a complaint may wait weeks to hear back from the plan responsible for resolving it. We believe that such delays cause unnecessary frustration for beneficiaries and are inconsistent with the customer service we expect from plans.

We acknowledge that our proposed timeframe for reaching out to the complainant concerning a CTM complaint is more specific than our requirement at §§ 422.564(b) and 423.564(b) for plans to ''promptly inform the enrollee whether the complaint is subject to its grievance procedures or its appeals procedures.'' We proposed a specific timeframe for contacting the beneficiary regarding a CTM complaint because, unlike with complaints received by the plans outside the CTM, the complainant has not reached out directly to the plan and may not know that their complaint has been passed on to the plan by CMS via the CTM. Moreover, as previously noted, CMS monitors the handling of complaints it receives through the CTM in real time. Part of handling CTM complaints through the CTM, as required by §§ 422.504(a)(15) and 423.505(b)(22), is entering information into the CTM when the plan reaches out to the complainant. CMS will therefore be able to monitor whether a plan has reached out to a beneficiary within the required timeframe and follow up with the plan well before timeframe for resolving the complaint has elapsed.

We proposed a three (3) calendar day timeframe for reaching out to the individual filing the complaint because it will provide a timely update to individuals filing both urgent and uncategorized complaints without delaying resolution of immediate need complaints. We expect that a plan will indicate in this communication that the plan has received and is working on the complaint, and that they provide contact information that the individual filing the complaint could use to follow up with the plan regarding the complaint. We solicited comment on whether this timeframe is appropriate and whether a longer or shorter timeframe will better balance the needs of beneficiaries with the capacity of plans to respond to complaints.

We also proposed conforming changes to §§ 422.504(a)(15) and 423.505(b)(22) to incorporate the proposed new requirements into the existing contractual requirements for MAOs and Part D sponsors. The proposed revisions to §§ 417.472(l) and 460.119 incorporate both the requirements in proposed § 422.125 and the requirement for a contract term for resolving complaints received by CMS through the CTM for Cost plans and PACE organizations and their contracts with CMS.

We received comments on the proposal and our responses to the comments are below.

Comment: Several commenters supported the proposed rule, with one noting that they support any effort to improve the timeliness and transparency associated with enrollee complaints to MA plans. One organization was particularly appreciative of CMS's goal to ensure that beneficiaries receive a timely response to complaints. Another commenter likewise expressed the need to codify a timeline for letting complainants know that the plan had received the complaint, stating that beneficiaries and their representatives frequently have no idea if a plan has received and is addressing the complaint.

Response: We appreciate the support for our proposal. We agree that establishing clear timelines for MA plans, Cost plans, PACE organizations and Part D plans to respond to CTM complaints is important.

Comment: A few comments supported the proposal and suggested that CMS adopt measures to promote greater transparency and accountability for beneficiary and provider complaints. Specifically, they suggested making CTM complaints publicly available on Medicare Plan Finder or elsewhere, carefully monitoring trends in CTM complaints and use them to focus CMS audits, creating an online portal for all stakeholders to enter complaints about plans, and creating a provider hotline similar to 1–800–MEDICARE specifically for providers to submit complaints.

Response: We appreciate the commenter's support. While the commenter's suggestions are out of scope for the proposed rule, we will consider them as we continue to explore ways to improve transparency and accountability. We already closely monitor CTM complaints and that complaint rates are used to calculate Star Ratings for MA and Part D plans.

Comment: A commenter supported the proposal, but expressed concern that many CTM complaints appear to be the result from MAO attempts to shield denials of coverage from review by the Independent Review Entities (IREs) that handle reconsiderations of adverse appeals and coverage determination decisions by MAOs and Part D sponsors. The commenter was particularly concerned that CMS does not appear to have an effective mechanism to monitor what should have been sent to the IRE for review but was not.

Response: This comment is out of scope for this proposal, but we appreciate the commenter's concern. We agree it is critical for MAOs, Part D sponsors and cost plan organizations (which must comply with the MA appeal regulations per § 417.600) to send all of the cases to the IRE that should be sent to the IRE. See section VII.E of this rule for a discussion of our revision to the process for identifying data completeness issues at the IRE and calculating scaled reductions for the Part C appeals measures to help ensure that all of the cases that should be sent to the IRE are sent.

Comment: A commenter expressed concern with CMS's statements that CTM complaints must be handled as appeals or grievances when appropriate. The commenter stated that treating all CTM complaints as appeals or grievances would result in conflicting timeframes for resolution and duplicative communications to members. The commenter requested clarification of whether CMS expects all complaints to be treated as appeals or grievances and, if not, whether complaints that are appeals or grievances would be held to the CTM timeframes in addition to the appeals and grievance timeframes.

Response: We understand the commenter's concern. We wish to clarify that CTM complaints should only be treated as appeals or grievances when they otherwise meet the definition of appeals or grievances under the applicable regulations. We note that MA and Part D appeals and grievances must be resolved ''as expeditiously as the case requires'' and that this would require resolution of the appeal or grievance within the proposed timeframe for immediate need and urgent complaints if the appeal or grievance involved a service or drug for which the beneficiary has a need that meets the definition of ''immediate need'' or ''urgent'' that we proposed and are finalizing in §§ 422.125 and 423.129. See §§ 422.564(e)(1), 422.630(e) and 423.564(e)(1) regarding the timeline for responses to enrollee appeals and grievances. Although the regulations at §§ 422.564(e)(2), 422.630(e)(2), and 423.564(e)(2) permit the 30-day timeframe resolution of grievances to be extended by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee, the stricter timing requirements for CTM complaints addressed in §§ 422.125 and 423.129

will control where a CTM complaint has been filed.

Similarly, PACE service determinations and appeals must be resolved as ''expeditiously as the participant's condition requires'', but no later than three days after the request is received for service determinations, 30 days after the request is received for appeals, and 72 hours after the appeal request is received for expedited appeals. See §§ 460.121(i), 460.122(c)(6), and 460.122(f) regarding the timelines for response to PACE participant service determination requests and appeals and the definition of expedited appeals. Pursuant to provisions of this rule, PACE grievances must also be resolved as ''expeditiously as the case requires,'' but no later than 30 calendar days after the PACE organization receives the grievance. See section XI.H of this rule, adopting changes to § 460.120, including a timeline for resolution of PACE grievances at § 460.120(g). Immediate need complaints that also qualify as PACE grievances, service determination requests, appeals, or expedited appeals therefore need to be resolved within two days under both PACE requirements and the requirements of this rule. Although the regulations at §§ 460.121(i)(1) and 460.122(f)(3) allow the timeline for resolution of service determination requests and expedited appeals to be extended by five days or 14 days, respectively, under certain circumstances, the stricter timing requirements for CTM complaints addressed in §§ 422.125 and 423.129 will control where a CTM complaint has been filed in the same way they would for MA and Part D grievances.

Because existing CMS regulations explicitly permit extension for MA and Part D appeals and grievances, we do not think it is appropriate to penalize an organization for extending the resolution of a non-immediate need and non-urgent CTM complaint that meets the definition of an MA or Part D appeal or grievance. Therefore we are adding a new paragraph (4) to §§ 422.125(b) and 423.129(b) to allow organizations to extend the timeline to respond to a CTM complaint if the complaint is also a grievance within the scope of §§ 422.564, 422.630 or 423.564 *and* if it meets the requirements for an extension of time under §§ 422.564€(2), 422.630(e)(2), or 423.564(e)(2) as applicable. (Depending on the type of organization—MA plan, applicable integrated plan, Part D plan, or cost plan the specific regulation that governs the time frame for responding to a grievance will vary.) This extension will not be available for any complaint that meets the definition of an immediate need complaint or urgent complaint or that requires expedited treatment under §§ 422.564(f), 422.630(d), or 423.564(f) because such a delay would present an unacceptable risk of harm to the beneficiary. PACE organizations are not permitted to extend the 30-day timeframe for resolution grievances under the revisions to § 460.120 finalized in this rule or for non-expedited appeals under § 460.122(c)(6) and service determinations must be resolved within eight days even with the permitted five-day extension under § 460.121(i), so it is not necessary to allow an extension of the 30-day timeline for non-immediate need and non-urgent complaints that also qualify as PACE grievances, service determination requests, or appeals.

We also acknowledge the potential conflict between the timelines for resolving immediate need complaints or urgent complaints and the requirement for organizations to respond within 24-hours to MA and Part D grievances that meet the definition of ''expedited grievances'' under §§ 422.564(f), 422.630(d), and 423.564(f). Similarly, there is a potential conflict between the timeline for resolving urgent complaints and the three days and 72 hours permitted to respond to PACE service determination requests and expedited appeals under §§ 460.121(i) and 460.122(f)(2). We did not intend to allow organizations to take longer to resolve an expedited MA or Part D grievance or PACE service determination request or expedited appeal than is currently required under the regulation merely because the grievance, service determination request, or appeal was received as a CTM complaint. Therefore, we are adding a new paragraph (5) to §§ 422.125(b) and 423.129(b) to make clear that organizations must comply with the shortest applicable timeframe for resolving a CTM complaint when the complaint also qualifies as a grievance, PACE service determination request, or PACE appeal. By shortest applicable timeframe, we mean the timeframe that (1) applies under this new CTM provision for the type of complaint (that is, immediate need complaint, urgent complaint, or other type of CTM complaint), the grievance regulation (that is §§ 422.56, 422.630, 423.564, or 460.120), or the PACE service determination or appeals regulation (that is §§ 460.121 or 460.122) and (2) is the shortest of those two applicable time frames. So, if a CTM complaint qualifies as both an urgent complaint and an expedited MA or Part D grievance, the organization responsible for responding to the complaint would be required to do so within 24 hours, as required by §§ 422.564(f), 422.630(d), and 423.564(f), and not within the seven days permitted under §§ 422.125(b)(2) and 423.129(b)(2) for urgent complaints. Similarly, with respect to the requirement for organizations to contact the individual making the complaint in the CTM within a specific timeframe, we expect that organizations will meet this timeframe for CTM complaints that also meet the definition of MA, Part D, or PACE grievances. To the extent that the requirement in §§ 422.564(b) and 423.564(b) to ''promptly inform the enrollee whether the complaint is subject to its grievance procedures or its appeals procedures'' would permit organizations to take longer than seven days to notify enrollees, §§ 422.125(c) and 423.129(c) would nevertheless require organizations to contact individuals who file a complaint that qualifies as a grievance in the CTM within seven days.

Comment: A commenter recommended shorter timeframes for resolving complaints submitted in the CTM. The commenter urged CMS to require that immediate need complaints be resolved within 24 hours and that all other cases be resolved within 72 hours. The commenter noted that this would reflect timelines for the appeals processes for Part B drugs and Part D benefits, which require that decisions be made ''as soon as the beneficiary requires'' but not later than 72 hours for standard requests (§§ 422.568 and 423.568) and 24 hours for expedited requests (§§ 422.572 and 423.572). The commenter noted that a seven-day resolution timeline for urgent complaints in which patients have three to fourteen days of treatment left would potentially leave patients without needed care for four days.

Response: We acknowledge that some complaints may require quicker resolution than the timeframes currently required for CTM complaints. As previously discussed, we expect organizations to treat complaints that meet the definition of appeals or grievances in a manner consistent with the requirements prescribed in the regulation for handling appeals and grievances. When a CTM complaint is actually an appeal, the organization must comply with the appeal regulations; nothing in the new regulations we are finalizing to address handling of CTM complaints changes or creates an exception to the appeal regulations that apply to cost plans, MA plans (including applicable integrated plans), Part D plans or PACE

organizations. We are finalizing a new paragraph (b)(4) as part of §§ 422.125 and 423.129 to make clear that organizations should comply with the shortest timeline called for in the applicable regulations when the timeliness requirements related to CTM complaints and grievances both apply. Therefore, an organization would have to respond to an immediate need complaint that also meets the definition of an expedited grievance within the 24 hours required by §§ 422.564(f), 422.630(d), or 423.564(f). Similarly, if an urgent complaint meets the definition of a grievance under §§ 422.561 and 423.560, or a PACE service determination request or appeal under §§ 460.121 and 460.122, and involves a beneficiary with only four days of medication remaining, the organization would be required to resolve the issue within four days because §§ 422.564I(1), 422.630(e), 423.564(e)(1), 460.121(i), and 460.122(c)(6) require organization notify an enrollee of its decision on a grievance (or PACE service determination request or appeal) ''as expeditiously as the case requires'' based on the enrollee's health status.

The resolution timeframes of two days for immediate need complaints, seven days for urgent complaints, and 30 days for all other CTM complaints have been in effect for many years and we do not have evidence that beneficiaries entitled to quicker resolutions under the regulations for grievances have had those resolutions delayed as a result. We are finalizing the resolution timeframes for CTM complaints as proposed in §§ 422.125 and 423.129 with the modifications described for §§ 422.125(b)(4) & (5) and 423.129(b)(4) & (5), but we will continue to monitor CTM complaint resolutions and appeals and grievances procedures and records for evidence that the CTM resolution timeframes are causing unnecessary delays in the resolution of appeals and grievances.

Comment: A commenter supported the proposed requirement to contact complainants within three days of filing a CTM complaint but recommended that CMS require organizations to provide beneficiaries with the CTM complaint ID number in addition to the plan contact information. The commenter also recommended that CMS require plans to document the contact within one to two business days of making the contact.

Response: We appreciate the commenter's support. We agree that organizations should provide the complainant with the CTM complaint ID number when reaching out to them regarding the complaint. However, we do not believe that it is necessary to codify this expectation at this time. Individuals filing CTM complaints receive the complaint ID number when they call 1–800–MEDICARE, and we do not think organizations reaching out to complainants would ordinarily fail to provide this information when contacting the individual to update them on the status of the complaint. We also agree that organizations should update the CTM promptly when contacting complainants and resolving complaints. We currently monitor CTMs on an ongoing basis and our experience is that organizations meet this expectation. Therefore, we do not believe that it is necessary to codify this expectation at this time.

Comment: A commenter noted that their State guidance requires health plans to acknowledge a complaint within ten days. They questioned whether there was a way to align the CMS requirement with the State requirement.

Response: We recognize that States may have different expectations with respect to handling complaints. However, State insurance laws other than licensure and solvency do not apply to MA plans under section 1856(b)(3) of the Act, and we do not believe that it is necessary or practical to allow organizations a longer time to contact complainants or resolve complaints merely because a State may permit longer timeframes for other types of health plans. We expect and will continue to expect MA plans, cost plans, Part D plans, and PACE organizations to meet the federal timeframes for beneficiary contact and complaint resolution adopted here (or in other applicable laws).

Comment: A commenter was generally supportive of the proposal but noted that complaints related to D–SNPs may require action from State Medicaid agencies, which may require longer to resolve. The commenter recommended that CMS modify the proposal to account for the need to involve State Medicaid agencies in the resolution of D–SNP complaints.

Response: We appreciate the commenter's support and acknowledge that some complaints for D–SNPs may require action by or input from State agencies or others that are not bound by CMS requirements. However, we do not believe a modification related to potential involvement of a State Medicaid agency to the requirements we proposed and are finalizing in this rule is necessary. Some CTM complaints have always required action by or input from outside agencies. This has not caused any significant delays in complaint resolution. Our experience is that most States recognize the need to resolve urgent complaints and immediate need complaints quickly and that States rarely take longer than 30 days to respond to other complaints. Isolated complaints may take longer to resolve as a result of inaction by outside agencies, but we do not believe that it is necessary to extend the timeframe for resolution to account for these outlier events. Rather, we will continue to exercise its discretion to take into account such outliers when determining whether compliance or enforcement actions are necessary in a particular circumstance.

Comment: A few commenters expressed concern that CMS would expect organizations to actually make contact with beneficiaries within the required timeframes, rather than requiring them to attempt to make contact. They requested that CMS clarify whether an attempt to make contact within the specified timeframe would satisfy the requirement. They also requested that CMS clarify the means by which the organization make contact.

Response: We recognize that beneficiaries are not always available to receive calls when plans reach out to them. We are therefore finalizing the proposed regulations at §§ 422.125(c) and 423.129(c) rule with a modification to clarify that organizations *attempt* to make contact with individuals filing complaints in the CTM within the specified timeframe. We believe that this ensures that plans will reach out to complainants in a timely manner without creating an unrealistic expectation that plans be able to reach complainants who may not be available to receive calls or other communications within the specified timeframes.

We also recognize that plans have many ways to contact beneficiaries, including by phone or mail. We expect plans to attempt to contact complainants regarding time sensitive matters by the most expeditious means available. We also expect that plans would generally use the same method to reach out to complainants as the complainants used to file complaints. Generally, this would require that plans attempt to contact complainants by phone, since this is the way the vast majority of complaints are made and the quickest way to reach individuals in real time. Our experience operating the CTM indicates that organizations do attempt to contact complainants by phone. We therefore do not believe that it is necessary to explicitly codify this expectation at this time. However, we

will continue to monitor CTM complaints to ensure that organizations continue to observe best practices for reaching out to complainants.

Comment: Several commenters requested greater flexibility in the timeframes for resolving CTM complaints and reaching out to individuals filing complaints. Some requested that CMS use a business day standard rather than a calendar day standard, stating that it would allow PACE organization to better manage communications outside of weekends and holidays. One commenter suggested extending the time period for contacting a complainant to five calendar days as an alternative to a business day standard to balance the need for timely communication against PACE organizations' need for flexibility. Another commenter was concerned that contacting the complainant within three calendar days of filing a complaint does not guarantee that the individual will get meaningful feedback and may result in beneficiary confusion regarding the status of their complaint. Some commenters believe that requiring contact within three calendar days for a complaint that MAOs and Part D sponsors have 30 days to resolve would negatively impact the resources needed to investigate and resolve immediate need and urgent cases. They noted that they already strive to reach out within four to seven days for urgent and uncategorized complaints. One commenter also noted that beneficiaries often express frustration with receiving calls at inopportune times, such as on holidays, especially when the complaint is not an immediate need complaint.

Response: We appreciate the commenters' desire for greater flexibility and the difficulty plans may experience in meeting a 3-calendar day timeframe for reaching out to beneficiaries. However, we do not believe that switching from a calendar day to a business day standard would be the best way to balance the needs of the beneficiary for transparency with the plans' needs for flexibility. The need for health care services can occur at any time, regardless of holidays or business schedules. Moreover, different states and territories celebrate different holidays, making it difficult for us to hold plans accountable to a uniform standard that is based on business days. We have long applied a calendar day standard to requirements related to complaints, as well as to appeals and grievances. It would therefore be inconsistent to switch to a business day standard when codifying CTM resolution requirements.

We also do not share the commenter's concern that contacting complainants before a complaint has been resolved would be premature or confusing. As discussed previously, one of the major purposes of requiring organizations to contact individuals filing complaints before the complaint has been resolved is to ensure that the complainant knows that the organization has received and is working to resolve the complaint. We do not believe such communications would be confusing for beneficiaries.

However, we do recognize that a three-calendar day requirement to contact beneficiaries is a new requirement that may prove difficult for organizations to adhere to and that it may not significantly improve the beneficiary experience such that burden is sufficiently outweighed. Based on these comments, we are finalizing a slightly longer deadline by which organizations must attempt to contact individuals filing non-immediate need complaints as finalized §§ 422.125(c) and 423.129(c) require organizations to attempt to contact the complainant within 7 calendar days of the organization being assigned the complaint from the CTM. We believe that this strikes a balance between providing individuals timely information regarding the handling of their complaints with plans' valid concerns about being able to meet a shorter timeframe. We also believe that this will address commenter's concerns about the difficulty of contacting beneficiaries on non-business days—it is unusual for an organization to have more than two or three consecutive non-business days in a 7-day period, so organizations should be able to meet the longer 7-day timeframe regardless of whether a complaint was received immediately before a weekend or holiday.

Final Decision: We thank commenters for their input. We note that comments were generally supportive, with many commenters representing plans requesting more flexibility and some commenters representing beneficiaries and providers requesting more stringent requirements and improved transparency. We received several comments requesting greater public transparency for CTM complaints and increased scrutiny of plans' handling of appeals and grievances that were out of scope for the proposal, but which we will take into account as we continue to monitor plan performance in these areas. Based on the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed rule with four significant modifications: (1) changing the requirement to make contact to a requirement to attempt contact, (2) adding language that permits the extension of time to resolve non-immediate need and non-urgent complaints that also qualify as non-expedited grievances in a manner consistent with the extension permitted for grievances under §§ 422.564, 422.630, and 423.564, (3) adding language that requires organizations to adhere to the shortest timeframe required by the regulation for CTM complaints and grievances when a CTM complaint also qualifies as a grievance; and (4) requiring that organizations contact individuals filing complaints within 7 calendar days rather than 3 calendar days.

N. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

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. Section 1860D–11(e)(2)(D) of the Act specifically permits approval only if the Secretary does not find that the design of the plan and its benefits, including any formulary and tiered formulary structure, are likely to substantially discourage enrollment by certain Part D eligible individuals. Section 1860D–4(c)(1)(A) of the Act requires ''a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.'' Lastly, 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 covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug.

In section III.Q., Changes to an Approved Formulary, of the December 2022 proposed rule, we proposed regulations related to (1) Part D sponsors obtaining approval to make changes to a formulary already approved by CMS, including extending the scope of immediate formulary substitutions (also generally referred to as immediate substitutions herein);[45] and (2) Part D

[45] In the subsequent November 2023 proposed rule, we noted the distinction between formulary substitutions made by a plan sponsor and product substitutions made by a pharmacist at the point of dispensing. As we described in section III.F.2.a.(2) of the November 2023 proposed rule, state laws

Continued

sponsors providing notice of such changes.

For reasons discussed therein, the December 2022 proposed rule proposed regulatory changes on how to obtain approval to make changes to a formulary already approved by CMS and to provide notice of such changes. We proposed 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.

Approval of formulary changes: Specifically, we proposed 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 proposed to 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 the request if it does not hear back from CMS within 30 days of submission, and at § 423.120(e)(3)(ii) to specify that Part D sponsors must not implement any non-maintenance changes until they receive notice of approval from CMS. We also proposed 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).

In support thereof, we proposed to define ''negative formulary changes'' to Part D drugs in § 423.100 to include drug removals, moves to higher cost-sharing tiers, and adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. We proposed to specify that negative formulary changes can be classified in one of three categories, which we also proposed to define in that same section as—

- ''Maintenance changes,'' which we proposed to 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 proposed to 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 we proposed to encompass 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 the removal of drugs ''deemed unsafe'' by FDA or ''removed from the market by their manufacturer.'' We proposed in the December 2022 proposed rule to move and incorporate that regulation text as follows: In § 423.120(e)(2)(i), we proposed to permit ''immediate substitutions,'' meaning Part D sponsors could make immediate 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 proposed to 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 also defining ''biological product,'' ''brand name biological product,'' and ''reference biological product'' in § 423.4. In proposing in § 423.120(e)(2)(ii) to continue to permit plans to immediately remove from their formulary any Part D drugs deemed unsafe by FDA or withdrawn from sale by their manufacturer, we proposed to newly describe these changes as ''market withdrawals.'' Under § 423.120(e)(2), as proposed in the December 2022 proposed rule, 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. However, proposed § 423.120(f)(2) and (3) would require Part D sponsors to provide advance general notice of such changes and to submit specific changes with their next required or scheduled CMS formulary updates.

We proposed in respective §§ 423.120(b)(3)(i)(B) and 423.120(e)(4) to conform our regulations such 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 (previously we only specified in regulation that this exception applied to immediate generic substitutions).

We also proposed to update and move to a new place 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 proposed to update such regulation 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).

We also proposed miscellaneous changes in § 423.100 in support of the previously described changes, including 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.

Permitted formulary changes and the IRA: We also proposed in the December 2022 proposed rule a change related to the Inflation Reduction Act of 2022 (IRA). Section 11001 of the IRA added section 1860D–4(b)(3)(I)(i) of Act to require, starting in 2026, Part D sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act 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 clarifies 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 proposed 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.

Notice of formulary changes: We proposed to move, with some revisions and streamlining, current regulations on

govern the ability of pharmacists to substitute biological products at the point-of-dispensing. By contrast, the Secretary's statutory authority under section 1860D–11(e)(2) of the Act governs approval of, and by extension any changes to, Part D formularies. The provisions we describe herein strictly apply to changes to Part D formularies made by plan sponsors, and do not apply to substitutions made by pharmacists at the point of dispensing.

notice of changes, and align them with our proposed approval requirements. Specifically, in § 423.120(f)(1) we proposed to specify that maintenance and non-maintenance negative formulary changes would require 30 days' advance notice to CMS, other specified entities, and in written form to affected enrollees. We proposed 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 the point of sale as specified. We also proposed to move and extend our existing requirements for immediate generic substitutions to include immediate substitutions of corresponding drugs and market withdrawals, by requiring 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 proposed 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 proposed at § 423.120(f)(4) to reorganize and renumber our current requirements for the contents of the direct written notice, and to provide more flexibility by no longer restricting appropriate alternative drugs to those in the same therapeutic category or class or cost-sharing tier. Our proposed revision aimed to make clear that the contents of the written notice would be largely the same regardless of the timing: whether Part D sponsors were 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) as proposed). Section 423.120(f)(5) proposed to newly specify how to provide advance general notice and specific notice of changes other than negative formulary changes.

We also proposed conforming amendments to update § 423.128(d)(2)(iii) to require online notice of ''negative formulary changes'' and to update cross citations in §§ 423.104(d)(2)(iv)(A)(6) and 423.128(e)(6) to reflect the fact we proposed to move the bulk of our requirements on formulary changes from § 423.120(b)(5) and (6) to § 423.120(e) and (f). We proposed 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).

After receiving comments on the December 2022 proposed rule, we identified a limited number of changes that we wanted to make to that proposed regulatory text, which we proposed in the November 2023 proposed rule. We noted that the November 2023 proposed rule reflected our intent to consider the formulary change proposals in section III.Q. of the December 2022 proposed rule, as updated by the limited changes proposed in the November 2023 proposed rule, for inclusion in future rulemaking.

In the November 2023 proposed rule, we noted that commenters on section III.Q. of the December 2022 proposed rule did not agree on the requirements that should apply to formulary substitutions of Food and Drug Administration (FDA) approved and licensed biosimilar biological products. Different commenters submitted divergent requests that formulary substitutions of biosimilar biological products other than interchangeable biological products be treated as immediate substitutions, be treated as maintenance changes, or not be permitted whatsoever. Our proposed regulatory text in the December 2022 proposed rule only addressed substitution of interchangeable biological products and unbranded biological products, and did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products. We stated that we believed, in part because of the interest in the topic, it would be appropriate to propose changes then to solicit comment directly on the subject.

Accordingly, we proposed in the November 2023 proposed rule to update the regulatory text we proposed in the December 2022 proposed rule to the extent necessary to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as ''maintenance changes,'' as defined in the December 2022 proposed rule. We also proposed to define a new term, ''biosimilar biological product,'' distinct from our previously proposed term ''interchangeable biological product.'' We also proposed some technical changes to the term ''interchangeable biological product.'' We believe these proposals from the November 2023 proposed rule add to the December 2022 proposed rule to increase access to biosimilar biological products in the Part D program, consistent with the Biden-Harris Administration's commitment to competition as outlined in Executive Order (E.O.) 14306: ''Promoting Competition in the American Economy.'' [46]

We specifically proposed to define biosimilar biological products consistent with sections 351(i) and (k) of the Public Health Service Act (PHSA) to include interchangeable biological products. As we noted in section III.F.2.b.(1) of the November 2023 proposed rule, in section III.Q of the December 2022 proposed rule, we originally proposed to permit maintenance changes and immediate substitutions involving interchangeable biological products. In the November 2023 proposed rule, we also proposed to allow substitution of biosimilar biological products other than interchangeable biological products for reference products as a maintenance change. To ensure clarity, we proposed in the November 2023 proposed rule to address the application of these policies to interchangeable biological products and to biosimilar biological products other than interchangeable biological products in separate paragraphs of the proposed definition of maintenance change in § 423.100.

Further, in considering a comment on immediate formulary substitutions we received on the December 2022 proposed rule, we also determined it would be appropriate to propose in the November 2023 proposed rule to provide Part D sponsors with additional flexibility with respect to the timing requirements for maintenance changes and immediate substitutions than as originally proposed in the December 2022 proposed rule. Rather than requiring a Part D sponsor to add a ''corresponding drug'' and make a ''negative formulary change'' (as both such terms are defined in the December 2022 proposed rule) to its related drug ''at the same time'' for a maintenance change, we proposed in the definition of maintenance change in § 423.100(1) in the November 2023 proposed rule to allow Part D sponsors to make a negative formulary change to the related drug within 90 days of adding the corresponding drug. We made similar changes in § 423.100(2) requiring negative formulary changes be made to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product. This means that the same flexibility is available when Part D sponsors make any biosimilar biological product substitutions that are maintenance changes. Lastly, we also

[46] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.*

proposed to make similar adjustments to the timing requirements for immediate substitutions of corresponding drugs in § 423.120(e)(2)(i). Specifically, as proposed in the November 2023 proposed rule, Part D sponsors would be able to make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug (as such terms are defined in the December 2022 proposed rule, as updated by the November 2023 proposed rule).

Additionally, we also proposed in the November 2023 proposed rule a technical change to our proposed definition of ''corresponding drug'' in § 423.100 included in the December 2022 proposed rule to specify that the reference to an ''unbranded biological product of a biological product'' is intended to refer to ''an unbranded biological product marketed under the same BLA [Biologics License Application] as a brand name biological product.''

Lastly, we proposed in the November 2023 proposed rule to address a technical change to the regulatory text proposed in the December 2022 proposed rule to specify in introductory language to the § 423.100 proposed definition of ''maintenance change'' that maintenance changes apply with respect to ''a covered Part D drug.''

As discussed earlier, we noted in the November 2023 proposed rule that we intended to consider section III.Q. of the December 2022 proposed rule, as updated by the limited proposed changes discussed in that November 2023 proposed rule, for inclusion in future rulemaking. Even though we acknowledged in the November 2023 proposed rule at a high level some comments regarding the December 2022 proposed rule that informed the limited changes we proposed in the November 2023 proposed rule, we stated that if we were to move forward in future rulemaking, we would respond to comments received in response to section III.Q. of the December 2022 proposed rule, as well as comments received in response to the changes proposed in section III.F. of the November 2023 proposed rule. We summarize those comments, and our responses as follows:

Comment: Many commenters voiced general and specific support for the proposals both in the December 2022 and November 2023 proposed rules. Somewhat fewer commenters offered criticism, in whole or in part, including some commenters who generally supported the proposals but had concerns with specific parts.

Response: We thank supporters for their support and all commenters for providing us with their feedback. We address specific comments about the proposals in more detail below.

Comment: Several commenters supported that our proposal in the December 2022 proposed rule codified rules on formulary changes in one place, with a few appreciating the clarity. A few supporters also specifically supported certain proposed definitions such as ''negative formulary change''; ''maintenance change'' and ''non-maintenance change''; and ''affected enrollee.'' Conversely, a few commenters suggested that we change certain definitions (as discussed in specific comments and responses below). Another commenter stated that the policy was too complex and required streamlining rather than a discussion in two preambles, and suggested we use a chart and that we not only explain the relationship of our proposals to Chapter 6 of the Prescription Drug Benefit Manual [47] but also update that manual chapter. A few other commenters stated that the proposed regulation did not conform to the guidance in Chapter 6.

Response: We thank those commenters who supported our proposal and specific definitions. One of our major goals with this proposal was to codify in one place guidance that had long stood apart from related regulations and conform the two in a reorganized regulation. We acknowledge that the policy related to changes to an approved formulary has been and remains intricate and that the December 2022 proposed rule and November 2023 proposed rule addressed a wide range of issues related to formulary changes, including with respect to conforming current regulations and longstanding guidance, while proposing new policies (for example, related to substitutions of biosimilar biological products). We will take the chart suggestion under consideration for any future updates to guidance and Chapter 6, but we do not think that the final rule is the appropriate location for such a chart. Where there is a conflict between the regulations and the manual chapter, the regulations supersede and take precedence. We discuss substantive issues related to interpretations of manual guidance later in these responses.

Comment: A commenter stated that CMS should not distinguish between authorized generic drugs and unbranded biological products in formulary placement policy because they are approved or licensed (respectively) under the same New Drug Application (NDA) or BLA as the brand name drug and, other than the fact that they are not labeled with a brand name on their label, they are the branded product. A product that is identical in all respects because it is approved or licensed under the same NDA or BLA should not be considered a ''negative'' formulary change, immediate or otherwise.

Response: While the commenter is technically correct that we could look at formulary replacement of a branded drug product with its authorized generic or unbranded biological product, as applicable, as not being a formulary change at all, we do not think this would be a meaningful distinction for enrollees.

When an enrollee goes to the pharmacy, they would not know the difference between an authorized generic drug or a generic drug as those terms will be defined in § 423.4. Similarly, if the name changes from the branded biological product to an unbranded biological product licensed under the same BLA, an enrollee might not know the difference between the unbranded biological product and a biosimilar of the branded biological product. Consequently, to avoid enrollee confusion, we are finalizing a rule that treats all these replacements as substitutions.

Comment: A commenter thanked CMS for the steps we proposed to take to eliminate ''barriers'' for patients to access lower-cost treatment options by permitting plans to add biosimilar biological products to formularies as they become available, while another commenter suggested that requiring 30 days' notice before the effective date of maintenance changes was an unnecessary ''barrier'' to patients getting the exact treatment they need.

Response: There have never been any barriers to Part D sponsors adding at any time to their formularies any Part D drugs that they think their enrollees need for treatment (such as new biosimilar biological products) or from adding those drugs on lower cost-sharing tiers or with fewer restrictions than those that apply to related drugs already on the formulary (such as reference products). Our guidance in section 30.3.3.1 of Chapter 6 of the Prescription Drug Benefit Manual states that Part D sponsors may add any Part D drug to their formularies at any time. We note, however, that we have and continue to maintain approval and notice requirements that Part D sponsors must follow when they seek to remove

[47] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

a drug or make negative formulary changes to drugs already on the formulary and that enrollees may currently be taking.

Comment: Several commenters stated we should not permit any midyear changes to formularies because enrollees enroll in plans with the expectation that they will have access to the same drugs for the entirety of the plan year and to permit any changes is tantamount to a bait and switch. A few commenters suggested that CMS should not permit any midyear formulary changes because enrollees cannot leave plans midyear, with one commenter requesting a special enrollment period (SEP) for enrollees to join other plans midyear following formulary changes.

Response: We do not agree that formularies should be static for the plan year. As discussed more fully in section III.Q.2.a. of the December 2022 proposed rule, section 1860D–4(b)(3)(E) of the Act itself contemplates that Part D sponsors may make changes to formularies during a plan year. For example, there is a need for certain changes to an approved formulary to reflect the availability of new drug therapies as well as for Part D sponsors to take advantage of opportunities to improve safety and quality and lower costs.

We understand that enrollees sign up for plans with the expectation of continued access to their drugs. Accordingly, we have established, and are codifying in this final rule, approval and notice requirements for different kinds of formulary changes. We are permitting the following changes to drugs currently provided on a formulary: (i) immediate substitutions of corresponding drugs, such as new generic drugs for brand name drugs and interchangeable biological products for reference products; (ii) immediate removal of drugs withdrawn from sale by their manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons; (iii) maintenance changes, which include substitutions of generic drugs for brand name drugs that are not being made on an immediate substitution basis; substitutions of interchangeable biological products for their reference products; and removals based on long term shortage and market availability; (iv) non-maintenance changes, which can only be made if CMS provides explicit approval and which do not apply to enrollees currently taking the applicable drug; and (v) enhancements to the formulary (for instance, Part D sponsors can add a drug to the formulary or lower its cost-sharing), which can be made at any time.

We believe these requirements strike the appropriate balance between protecting enrollees by ensuring they have adequate notice of changes to their plan's formulary, while ensuring Part D sponsors have the flexibility to ensure formularies reflect the latest market developments and clinical guidelines. We monitor negative change request submissions and changes to HPMS formularies as a matter of standard operations, and we are not aware of widespread complaints from beneficiaries stating they have been subject to formulary changes without proper notice. Part D sponsors submit all maintenance and non-maintenance changes to CMS for approval and, even if approved, non-maintenance changes do not apply to enrollees currently taking a drug for the remainder of the plan year. In addition, enrollees can avail themselves of the formulary exception process if the enrollee or their physician believes it is necessary that the enrollee remain on a drug that is subject to a midyear change. The request for a SEP based on a midyear formulary change is out of scope.

Comment: A few commenters specifically supported the time periods within which we required specific notice. A few other commenters pointed to the fact that section 30.3.4.1 of Chapter 6 of the Prescription Drug Benefit Manual requires 60 days' advance direct notice and asked that we conform any final regulation to that guidance.

Response: We appreciate commenters' support for the specific notice time periods that we proposed. Our intent in the December 2022 proposed rule was to codify much of our longstanding guidance. However, while Chapter 6 of the Prescription Drug Benefit Manual specifies a requirement for 60 days' advance direct notice, the current § 423.120(b)(5)(i) has required Part D sponsors to provide 30 days' notice rather than 60 days' notice for formulary changes since the effective date of 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 April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule). Where there is a conflict between the regulations and the manual chapter, the regulations supersede and take precedence. The same considerations for adopting a 30-day requirement that we discussed in the November 2017 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) (hereafter referred to the November 2017 proposed rule), and which led us to finalize the April 2018 final rule, strike us as applicable today. Additionally, we have several years of operational experience with the requirements of the April 2018 final rule, for which we have not received widespread complaints.

As discussed in section II.A.14 of the November 2017 proposed rule, we believe the 30 days' notice provides the necessary beneficiary protections and affords enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. CMS regulations establish robust beneficiary protections in the coverage determination and appeals processes. CMS requires at § 423.568(b) that standard coverage determinations are completed within 72 hours and at § 423.572(a) that expedited coverage determinations for exigent circumstances are completed within 24 hours. If an initial coverage determination is unfavorable, the enrollee or prescriber can request a standard redetermination, which in accordance with § 423.590(a) must be completed within 7 days of receipt of the request, or an expedited redetermination, which in accordance with § 423.590(d)(1) must be completed within 72 hours. (See a later response addressing comments supporting and opposing the advance direct notice requirements we would require for Part D sponsors seeking formulary to substitution of biosimilar biological products for reference products as maintenance changes.)

Comment: A commenter suggested that we no longer require any notification of immediate substitutions because it would be confusing to send a notice about a change that already took effect. In contrast, another commenter suggested that permitting sponsors to provide notice as late as almost two months after an immediate formulary substitution takes effect is too long a time period and asked that we not finalize the requirement to provide notice ''no later than the end of the month following any month in which a change takes effect.'' They suggested that such notice be provided on or before the effective date of the change. A few other commenters recommended that there should be advance direct notice for any changes made to a

formulary, including immediate substitutions.

Response: We disagree with the suggestion to do away entirely with requiring direct notice to affected enrollees of immediate substitutions. It is still important that affected enrollees learn about formulary changes made to the drugs they take, even in the context of immediate substitutions that may have already taken effect. For immediate substitutions, under proposed § 423.120(f)(2), and under current § 423.120(b)(5)(iv)(C), permitting immediate substitutions of generic drugs for brand name drugs, Part D sponsors must provide advance general notice in beneficiary communications materials describing the types of changes that can be made without giving advance direct notice of specific changes, including to enrollees currently taking a drug subject to substitution. Part D sponsors must specify in this advance general notice that affected enrollees will receive direct notice of any specific changes made to drugs they take, which may arrive after the change is effective, and that will explain steps they may take to request coverage determinations, including exceptions. Proposed § 423.120(f)(3) and current § 423.120(b)(5)(iv)(E) require that Part D sponsors provide retrospective direct notice to affected enrollees. Additionally, § 423.128(d)(2)(ii) requires Part D sponsors to update their online formulary monthly. However, we decline to require that notice be provided in advance or at the same time as the effective date of an immediate substitution. A central reason that we do not require advance direct notice of specific changes in these cases is to support and encourage Part D sponsors to add corresponding drugs to their formularies as soon as possible. We are not aware of a notable volume of enrollee complaints related to the notice requirements for immediate substitutions of generic drugs under the current § 423.120(b)(5)(iv), which we finalized in the April 2018 final rule to permit Part D sponsors to send retrospective direct notice of immediate generic substitutions to affected enrollees after such changes take effect. We do not believe that extending similar rules to immediate substitutions of authorized generics, interchangeable biological products, and unbranded biological products will have different results for enrollees and, therefore, we decline to change that regulation now or to require different notice requirements for immediate substitutions of products that qualify as corresponding drugs other than generics.

Comment: A commenter stated that there was a technical error in our definition of maintenance change proposed in § 423.100 because it failed to indicate that corresponding drugs must be newly available to align with sub-regulatory guidance at Chapter 6, section 30.3.3.1, of the Prescription Drug Benefit Manual, which the commentor interprets as requiring that maintenance changes involving brand-name drugs being substituted with generic drugs to be limited to newly available generic drugs only.

Response: The comment pointing to a technical error with respect to maintenance changes misinterprets our guidance. While section 30.3.3.1 of Chapter 6 provides an example of a maintenance change involving a new generic drug, our sub-regulatory guidance has not limited maintenance changes to only newly approved generic drugs. Notably, section 30.3.3.2 states that ''CMS will generally give positive consideration to the following types of formulary changes'' including ''[r]emoval or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a tier with lower cost to the beneficiary.'' It does not require that generic drugs added to the formulary as part of maintenance changes be newly available. However, to make an immediate substitution, the generic drug being added to the formulary must be newly available.[48] Although some sponsors might choose to make maintenance changes only to substitute newly marketed generics, we do not want to preclude sponsors from making maintenance changes to add generics that are not newly available because there are other appropriate factors that Part D sponsors could consider when determining when to make such formulary substitutions. For example, a Part D sponsor might not make a formulary substitution when a generic first becomes available on the market because there may not be a significant price difference between the first generic and brand name drug. However, as more generics are introduced to the market, the price of all generic drugs may decrease to the point a Part D sponsor could later decide a formulary change would be advantageous.

Comment: A few commenters supported all or parts of our proposal, as updated in the November 2023 proposed rule, to require Part D sponsors to remove, or otherwise apply a negative formulary change to, a brand name drug, reference product, or brand name biological product within 30 days of adding a corresponding drug as part of an immediate substitution (under proposed § 423.120(e)(2)(i)) or within 90 days of adding a corresponding drug or biosimilar biological product as part of a maintenance change (under subparagraphs (1) and (2), respectively, of the proposed § 423.100 definition of maintenance change). A few commenters did not support the change as proposed but had differing views on what the policy should be. One commenter stated that we must continue to require immediate substitutions to take place ''at the same time'' because there was no evidence that the existing requirement created a problem that needs to be fixed. A few other commenters asked that we provide more time than a 30- or 90-day window within which to apply a negative formulary change to a brand name drug or reference product after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product to the formulary. Another commenter said that we should apply the same 90-day window to both types of changes because implementing different time frames within which to complete immediate substitutions and maintenance changes could be burdensome for Part D sponsors and confuse enrollees, pharmacies, and providers. Another commenter stated that the 30- and 90-day windows did not provide enough time for Part D sponsors to evaluate new products' attributes and availability in the marketplace, update systems, and consider market condition for pricing changes (for instance, whether a generic price will drop even more after additional entries). Another commenter asked that we monitor this flexibility on an annual basis to ensure providing more time to complete immediate substitutions would not permit Part D sponsors to game the system by delaying coverage for generic drugs.

Response: We appreciate comments on both sides of the issue. We think 30- and 90-day limits to make negative formulary changes after adding a drug as part of an immediate substitution or maintenance change under

[48] Section 423.120(b)(5)(iv) requires in part that, ''The Part D sponsor previously could not have included such therapeutically equivalent generic drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such generic drug was not yet available on the market.'' In the proposed regulatory reorganization, this requirement would appear at § 423.120(e)(2)(i) and would apply to immediate substitutions of corresponding drugs.

§ 423.120(e)(2)(i) or subparagraphs (1) and (2) of the definition of a maintenance change in § 423.100, respectively, are reasonable. As for evidence to support our proposal, we proposed these flexibilities in our November 2023 proposed rule in response to a comment we received in response to our December 2022 proposed rule that stated it was difficult to make substitutions ''at the same time''. The commenter suggested that while they could quickly add a drug to the formulary, before removing or making negative formulary changes to a drug currently on the formulary they needed time to, for instance, evaluate new product attributes such as formulation, interchangeability, and pricing; determine sufficient availability in the marketplace; communicate changes; and update systems. In response to our November 2023 proposed rule, the original commenter repeated its concerns and a couple of other commenters also asked for more time. Additionally, a couple of commenters specified that they supported the 90-day window. We believe these comments, as well as our appreciation of formulary management considerations and the practicalities of programming internal systems, provide sufficient evidence to support the proposed timeframes.

To respond to commenters to the November 2023 proposed rule that asked for longer times frames within which to make negative changes to the drug on the formulary, the purpose of immediate substitutions is to support quick action, in which Part D sponsors put a newer corresponding drug on the formulary right away and remove the drug it replaces as soon as possible. To encourage this quick action, we permit Part D sponsors implementing immediate substitutions to provide notice to affected enrollees of the specific changes after they have taken effect. For that reason, we continue to encourage that immediate substitutions take place ''at the same time.'' Extending the time within which to remove a brand name drug, brand name biological product, or reference product past 30 days would negate the concept of an ''immediate'' change.

While maintenance changes are not as urgent a matter, it would be challenging for CMS to monitor negative formulary changes that take place more than 90 days after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product.[49] Further, the more days that pass after a Part D sponsor adds a replacement drug and before it removes or makes another other negative formulary change to the drug on the formulary it will replace, the more the two actions seem less like a substitution of one drug for another so much as two unrelated formulary changes.

In response to the concern that implementing different time frames to make immediate substitutions versus maintenance changes creates a burden for Part D sponsors, they are not required to take advantage of the flexibility offered. The respective 30- and 90-day timeframes to make a negative formulary change after adding a corresponding drug to the formulary are limits, not requirements. Under the proposal, a Part D sponsor could decide to ensure all immediate substitutions and maintenance changes take place ''at the same time.''

We have carefully considered the commenter's concern that implementing different windows could confuse enrollees, providers, and pharmacies. It is possible that Part D sponsors are currently removing brand name drugs after the date they add corresponding generic drugs. As discussed in our November 2023 proposed rule, there has been a longstanding operational limitation that Part D sponsors remove a brand name drug from the formulary within 90 days of adding a generic drug. We also do not believe that enrollees will be aware of the exact moment that a Part D sponsor decides to add a drug. Rather, affected enrollees will most likely learn that their plan will be making, or already has made, a formulary substitution either when they receive direct notice or request a refill on a brand name drug or reference product. We are not aware that the current limitation has resulted in undue confusion and do not expect that to be the case with this rule. We will also continue to review beneficiary complaints in our Complaint Tracking Module, should any complaints arise related to confusion about the different timeframes.

Lastly, we do not believe that monitoring immediate substitutions on an annual basis would provide a means to determine or address if Part D sponsors are gaming the system by delaying coverage for generic drugs because this provision has not and will not require Part D sponsors to offer generic drugs.

[49] Please note that the definition of corresponding drug in § 423.120 includes interchangeable biological products.

Comment: A commenter asked that we clarify whether we mean business or calendar days in all instances that apply a number of days to a requirement.

Response: For regulations related to notice and approval of changes to approved formularies, any requirements that refer to days are a reference to calendar days. This includes § 423.120(b)(5) and (6) and proposed (e) and (f) and related definitions including ''maintenance changes'' as defined in § 423.100. We believe the use of calendar days for regulations related to notice and approval of changes to approved formularies is appropriate because they are easier for CMS, plan sponsors, enrollees, and others to track.

Comment: Several commenters stated that maintenance changes did not require prior approval from CMS, with a commenter characterizing such changes as ''near-immediate.''

Response: While it is technically true that Part D sponsors may not receive explicit notice of approval of a negative change request for a maintenance change, the proposed § 423.120(e)(3)(i) would codify longstanding sub-regulatory guidance from Chapter 6, section 30.3.3.2, of the Prescription Drug Benefit Manual, under which Part D sponsors may assume a maintenance change request has been approved if they do not hear from CMS within 30 days of submission. This is in contrast to our longstanding policy for non-maintenance changes, which we proposed to codify at § 423.120(e)(3)(ii), under which Part D sponsors must not implement non-maintenance changes until they receive explicit notice of approval of the negative change request from CMS. Regardless of whether approval can be assumed after a period of time, contrary to the commenters' assertions, both longstanding guidance and our proposal require Part D sponsors to submit maintenance and non-maintenance change requests to CMS for approval. Moreover, it is important to note that approval of maintenance changes is not automatic. While we noted in our preamble to the November 2023 proposed rule that most such requests are routinely approved, CMS endeavors to review all requests and we have denied maintenance change requests, albeit infrequently, before the end of the 30-day approval period. Furthermore, we have instituted edits within the HPMS Negative Change Request module which can raise flags on issues that require our review or in some cases will prevent Part D sponsors from submitting a negative change request that would not meet CMS requirements. Lastly, should a Part D sponsor make a change to their HPMS

formulary file that is inconsistent with an approved (or assumed approved) negative change request, CMS may deny the formulary change via the line-level review process.

Comment: A couple of commenters asked CMS to expand the proposed definition of maintenance changes to include as additional categories of maintenance changes (1) applying PA to exclude non-Part D drugs or to reflect new indications or (2) placing PA or ST on protected class drugs specified under section 1860D–4(b)(3)(G)(iv) of the Act to ensure they are used for protected indications. Another commenter requested that CMS allow prescribers to continue to prescribe the reference product to an enrollee currently taking the affected product without a lengthy prior authorization requirement.

Response: We did not propose to permit the midyear addition of PA to prevent use of drugs for excluded uses, when a new indication is approved, or to permit Part D sponsors to cover only protected indications for protected class drugs. We appreciate commenters raising these issues, and we may take some of these suggestions into consideration for future rulemaking. Generally, we expect Part D sponsors to submit such PA or ST requirements for review and approval with their annual formulary submissions. Additionally, under current policy, Part D sponsors can submit these types of requests midyear as non-maintenance change requests for consideration by CMS. In the absence of a PA requirement on a particular drug, Part D plans may conduct retrospective review under § 423.153(c)(3) to confirm that a dispensed drug is being used for a medically accepted indication. We note that non-protected indications for protected class drugs are not excluded from Part D coverage as long as the use is for a medically accepted indication, as defined in section 1860D–2(e)(4) of the Act.

Our intent is to allow Part D sponsors to promote utilization of biosimilar biological products. We believe the current PA process continues to be the appropriate mechanism for providers to provide the necessary justification for continuing on a reference product.

Comment: A few commenters offered divergent views on our proposal that the list of alternative drugs, which we require under the current § 423.120(b)(5)(ii)(D) to be provided as part of the written notice of a formulary change, no longer be limited under our proposed § 423.120(f)(4)(iv) to alternative drugs in the same therapeutic category or class as the drug to which the negative formulary change applies. A couple of commenters were concerned that Part D plans would use this flexibility to switch patients under the immediate substitution rules to drugs with different forms or modes of therapeutic action. In contrast, a supporter noted that drugs may span multiple therapeutic categories and appreciated the extra flexibility provided for Part D sponsors to negotiate discounts and reduce overall prescription drug spending. Another supporter asked that we permit clinical experts outside of the P&T committee to identify appropriate formulary alternatives because P&T committees only meet quarterly.

Response: We appreciate commenters' support. For commenters that did not support our proposed policy, we clarify that the current requirement that Part D sponsors list alternative drugs in § 423.120(b)(5)(ii)(D) addresses a different topic than does the current regulation § 423.120(b)(5)(iv), which specifies drugs that can be immediately substituted. Section 423.120(b)(5)(ii) addresses the content that must be included in notices of change—including a list of alternatives—but, contrary to the commenters' suggestions, does not govern what types of drugs can be substituted or the conditions for making such changes. Rather, § 423.120(b)(5)(iv) governs what types of drugs can be immediately substituted and the conditions for making such changes.

While § 423.120(b)(5)(ii) does not govern the types of drugs that can be substituted, it requires Part D sponsors to list alternatives. We believe provision of this list could affect treatment in that it might provide alternatives that an enrollee and their provider have not considered, or steer the enrollee to certain drugs on that list given their coverage on their formulary. An enrollee and their provider can consider the list of alternatives to the drug that is being removed or otherwise subject to a negative formulary change as they decide whether to try the new drug added to the formulary, try another drug that appears on the list of alternatives, or to request an exception for coverage of the removed drug. As we noted in our proposal, there can be multiple drug options to treat the same condition and we believe that the list of alternatives should not limit possibilities of treatment by a strict adherence to class and category, particularly since Part D sponsors are not required to use a particular classification system for their Part D formularies. Therefore, we are finalizing § 423.120(f)(4)(iv) as proposed.

As to the question regarding who can determine what drug alternatives exist, we do not believe it is appropriate for Part D sponsors to outsource consideration of formulary alternatives to clinical experts outside of the P&T committee. Section 423.120(b)(1) specifies that a P&T committee must develop and revise the formulary. Applying a negative formulary change to a drug is a formulary revision, and we believe that consideration of the formulary in its entirety is part and parcel of any formulary revision decision. We do not see how, for example, a decision could be made to remove or apply utilization management restrictions to a drug without examining which drugs are being added to or are already on the formulary that could treat the same conditions as the drug subject to the negative formulary change.

Comment: A couple of commenters supported our proposal in the December 2022 proposed rule to identify § 423.120(e)(2)(i) as the successor regulation to § 423.120(b)(5)(iv) under section 1860D–4(b)(3)(I)(ii) of the Act, as added by the IRA. Another commenter asked us to clarify expectations for when a Part D drug that is a selected drug under section 11001 of the IRA is removed from the formulary and give plans the flexibility to determine lowest price on a drug-by-drug basis.

Response: We thank the commenters for their support. Section 1860D–4(b)(3)(I)(i) of the Act requires Part D sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price is in effect with respect to the plan year. Because maximum fair prices will not take effect until 2026, the formulary inclusion requirement in section 1860D–4(b)(3)(I)(i) of the Act does not apply in 2025. As a result, we are not finalizing the proposed language in § 423.120(b)(5) to identify a successor regulation for purposes of section 1860D–4(b)(3)(I)(ii) of the Act at this time.

It is not within the scope of this provision on formulary changes to address the request for flexibility to determine the lowest price of the drug.

Comment: A commenter pointed out that our regulation assumes all enrollees receive and comprehend notices of midyear formulary changes, whereas in reality enrollees may experience low health literacy, language barriers, or cognitive impairments that impede their understanding of such notices. Furthermore, the commenter noted that enrollees from socioeconomically disadvantaged communities and those experiencing major health challenges

such as rare diseases may not be capable of navigating the exceptions process. The commenter suggested that, by ignoring health disparities, our proposed policy for formulary substitution of biosimilar biological products as maintenance changes could cause disproportionate harm to vulnerable patient communities.

Response: We certainly appreciate that the health care system, along with all its complexities, presents significant challenges for those experiencing health care and other disparities. CMS continues to take action to address those disparities. However, we do not believe that our biosimilar biological product policy on maintenance changes widens health care disparities. In fact, our intent is quite the opposite. For example, if this proposal improves access to more biosimilar biological products in the Part D program, it could lead to greater utilization of lower price biosimilar biological products that have been determined by FDA to be just as safe and effective as their reference products.

CMS has implemented various requirements to help protect enrollees, address disparities, and mitigate confusion and burdens for enrollees, especially those with low health literacy, language barriers, and cognitive and other health care impairments. For example, under § 423.2267(a), we require Part D sponsors to provide: translated materials proactively in any non-English language that at least 5 percent of the beneficiaries in their service area speak, and materials in alternative formats (such as recordings and braille) to beneficiaries who are visually impaired. Furthermore, pursuant to § 423.128(d), we require all plans to have call centers to respond to current and prospective enrollee requests for assistance, and § 423.128(d)(1)(iii) also requires Part D sponsors to provide interpreters for non-English speaking and limited English proficient (LEP) individuals at their call centers. States also have established State Health Insurance Assistance Programs (SHIPs) that can assist enrollees in navigating their options. Enrollees can also designate a person to speak to plans on their behalf.

Comment: A commenter requested that we permit Part D sponsors to immediately substitute a brand name drug for an authorized generic, and an authorized generic drug for a generic drug, including within the same plan year. Another commenter asked that we make clear there could be only one maintenance change for a reference product within a single plan year to avoid confusion and potential disruption of care. A few other commenters asked us either to clarify or make sure that § 423.120(e)(2)(i) only permitted substitution of an interchangeable biological product for a reference product and not substitution of an interchangeable biological product for another interchangeable biological product that has the same reference product. Another commenter asked that we clarify that maintenance changes would only be allowed for biosimilar biological products for their reference products and not among different biosimilar biological products that have the same reference product. Without identifying them all, a commenter asked for guidance specific to 36 different permutations of formulary change types it counted among branded and unbranded versions of reference products and biosimilar biological products. In contrast, another commenter asked generally how Part D sponsors should treat enrollees taking a biosimilar biological product that is not the biosimilar biological product that is covered by the plan.

Response: We would not permit the immediate substitution of a brand name drug for an authorized generic (that is, applying a negative formulary change to an authorized generic already on the formulary and adding a brand name drug to the formulary). Our proposed regulation is not written to support that substitution. The proposed § 423.120(e)(2)(i) allows Part D sponsors to apply immediate negative formulary changes to a ''brand name drug. . . . within 30 days of adding a corresponding drug.'' The proposed definition of ''corresponding drug'' in § 423.100 refers in part to ''a generic or authorized generic of a brand name drug.'' Therefore, an immediate substitution would not allow a Part D sponsor to make a negative formulary change to an authorized generic within 30 days of adding a brand name drug. We do not support modifying our proposal in this way because the intent of our generic substitution policy is to encourage plans to make substitutions as soon as new generic drugs or authorized generic drugs are marketed to provide beneficiaries with access to lower cost therapeutically equivalent drugs. Moreover, it is unlikely that a brand name drug would be marketed after an authorized generic and, therefore, it would not fit within the structure of our proposed regulation, which contemplates the substitution within the plan year of a brand name drug to be removed or subject to a negative formulary change with a drug that is marketed (after CMS approves an initial formulary).

Likewise, our proposed regulation would not permit Part D sponsors to immediately substitute a generic for an authorized generic or an authorized generic for a generic as an immediate substitution under § 423.120(e)(2)(i). Nevertheless, an authorized generic and a generic of the same brand name drug generally are represented by the same RxCUI, as assigned by the National Library of Medicine's RxNorm.[50] In other words, one RxCUI can represent multiple NDCs. As more NDCs become available and assigned to an RxCUI, to the extent there is not a different RxCUI to submit on the formulary file, Part D sponsors cannot submit NDC-specific formulary changes in the HPMS system. Further, we note that it is not inconsistent with CMS policy for Part D sponsors not to cover every NDC associated with an RxCUI for a generic drug. Accordingly, a Part D sponsor can adjust which NDCs for a generic drug and authorized generic of the same brand name reference drug are covered on its formulary in a manner that would not be considered a formulary change subject to the requirements of this final rule.

With respect to interchangeable biological products, the proposed § 423.120(e)(2)(i) likewise would not permit immediate substitutions among interchangeable biological products—that is, we would not permit Part D sponsors to immediately substitute an interchangeable biological product for another interchangeable biological product as an immediate substitution under § 423.120(e)(2)(i). This is because § 423.120(e)(2)(i) would be limited to immediate substitutions of interchangeable biological products for their reference products, not for other interchangeable biological products that may be interchangeable with the same reference product. However, in contrast to generic drugs and authorized generic drugs of the same brand name drug sharing the same RxCUI, every biosimilar biological product is assigned its own distinct RxCUI. Therefore, a Part D sponsor cannot adjust which NDCs for interchangeable biological products with the same reference product are covered on its formulary in a manner that would not be considered a formulary change subject to the requirements of this rule. We believe this is in line with FDA's approach that approves biosimilar biological products in relation to reference products. For instance, our definition of a ''biosimilar

[50] *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

biological product'' at § 423.4 cites section 351(i)(2) of the PHSA (42 U.S.C. 262(i)(2)), which establishes similarity of a biological product compared to the reference product and not with respect to other biosimilar biological products. Similarly, our definition of an ''interchangeable biological product'' at § 423.4 cites section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)), which provides that interchangeability is determined with respect to a reference product and not with respect to other interchangeable biological products.

Our proposed definition of a maintenance change at § 423.100 would not permit substitutions among biosimilar biological products that share a reference product as maintenance changes, nor would our proposed definition of immediate substitutions at § 423.120(e)(2)(i) permit maintenance changes among interchangeable biological products that share a reference product. For interchangeable biological products, § 423.100 would define a maintenance change at subparagraph (1) as making any negative formulary change to a drug within 90 days of adding a corresponding drug as specified. Section 423.100 would define a corresponding drug to include ''an interchangeable biological product of a reference product''. For biosimilar biological products other than interchangeable biological products, § 423.100 would define a maintenance change at subparagraph (2) as ''making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product.'' This definition does not include making negative formulary changes to a biosimilar biological product after adding a different biosimilar biological product for the same reference product.

With respect to the commenter's question about how to treat enrollees taking a biosimilar biological product that is not the biosimilar biological product on the formulary, this situation would be treated the same as any other situation where an enrollee is taking a non-formulary drug. If the plan only has biosimilar biological product A on the formulary and then an enrollee who has been taking biosimilar biological product B enrolls in the plan, the enrollee would need a new prescription for the biosimilar biological product A.

We do not prohibit multiple maintenance changes with respect to the same drug within the same plan year, and our review process considers each such request on its own merit. We think multiple maintenance changes within the same year would be rare given the type of changes we allow but not impossible. For example, a plan may add a therapeutically equivalent generic drug to the formulary and add a PA to the brand name drug. If the brand name drug then becomes subject to a long-term shortage, a maintenance change to remove the brand name drug from the formulary altogether may be appropriate.

It is beyond the scope of this regulation to address every hypothetical scenario provided by the commenter, but we will take them into account when providing guidance in the future.

Finally, we note that, regardless of whether Part D sponsors are permitted to replace an existing drug, they can always add the generic or authorized generic, or biosimilar biological product or unbranded biological product, to their formulary.

Comment: Several commenters, including a few concerned only about the proposed expansion of immediate substitutions to include interchangeable biological products for reference products, asked that we require transition supplies for immediate substitutions, including for some generic substitutions of brand name drugs. Additionally, a few commenters, including commenters concerned that we would now permit as maintenance changes substitution of biosimilar biological products other than interchangeable biosimilar biological products for reference products, asked that we require Part D sponsors to provide transition supplies for midyear maintenance changes. A commenter asked that we explain how our rules apply to hypothetical transition scenarios.

Response: We do not agree with the commenters asking us to apply the transition process to immediate substitutions or maintenance changes. The current § 423.120(b)(3) provides that Part D sponsors must provide a transition process for specified enrollees. In the April 2018 final rule, we finalized the current § 423.120(b)(3)(i)(B) to provide that Part D sponsors do not need to provide a transition supply when a Part D sponsor immediately substitutes a generic drug for a brand name drug under § 423.120(b)(5)(iv). We are not aware of widespread complaints regarding this policy and therefore do not see a reason to undo a policy that has been in place for several years or to apply different rules to other kinds of immediate substitutions or to maintenance changes permitted under this proposal.

In the December 2022 proposed rule, we proposed to move the current regulation on immediate generic substitutions, § 423.120(b)(5)(iv), to § 423.120(e)(2)(i) and to expand it to include among other products, interchangeable biosimilar biological products. We also proposed in the December 2022 proposed rule to change the reference in § 423.120(b)(3)(i)(B) to now refer to § 423.120(e)(2), which would mean we would not require Part D sponsors to provide a transition supply, for instance, when replacing a reference product with an interchangeable biological product within the requirements of § 423.120(e)(2)(i). Similar to our decision in the April 2018 final rule not to provide transition supplies for immediate generic substitutions under § 423.120(b)(5)(iv), we are not convinced there is a need to require transition supplies for immediate substitutions of interchangeable biological products, authorized generics, or unbranded biological products under the proposed § 423.120(e)(2)(i). Requiring transition supplies for one type of immediate substitution but not others would introduce an unnecessary level of operational complexity for Part D sponsors and inconsistent policies.

With respect to requiring transition supplies for maintenance changes, we did not propose to change the existing transition policy. Maintenance changes require 30 days advance notice to affected enrollees under § 423.120(f)(1). That 30 days' advance notice serves the same function as the transition policy to provide affected enrollees time to consider a formulary alternative or pursue a formulary or tiering exception for the drug they are taking that will be subject to the negative formulary change. As a reminder, the transition regulation at § 423.120(b)(3)(i)(B) requires 30 days' notice and a month's supply. Similarly, affected enrollees getting 30 days advance notice of a maintenance change who have refills or obtain a new prescription can go to the pharmacy and request a refill before the maintenance change becomes effective.

It is beyond the scope of this regulation to address every hypothetical transition scenario, but we will take them into account when providing guidance in the future to reflect regulatory changes.

Comment: While many commenters generally supported greater use of biosimilar biological products, they were generally divided into three main groups regarding our specific proposals relating to biosimilar biological product substitutions (which we mean to describe generally as a formulary change in which a Part D sponsor would add a biosimilar biological product and either

remove or apply a negative formulary change to its reference product).

The first group of commenters supported some or all of our specific proposals regarding biosimilar biological product substitutions, under which we would permit immediate substitutions of interchangeable biological products for their reference products under proposed § 423.120(e)(2)(i) and also permit Part D sponsors to treat as maintenance changes all biosimilar biological product substitutions under subparagraphs (1) and (2) of the definition of maintenance changes proposed in § 423.100. They stated, for instance, that the proposed policies would result in more uptake of biosimilar biological products by switching enrollees taking reference products to biosimilar biological products, a move they felt could improve the overall affordability of the Part D program to enrollees due to the lower cost of biosimilar biological products as compared to reference products. They stated, for instance, that because a distinction is made between interchangeable biological products and biosimilar biological products other than interchangeable biological products, with respect to pharmacy-level substitutions, CMS had struck the right balance by proposing to provide 30 days' advance notice to enrollees to get a new prescription or to ask for an exception before a Part D sponsor substitutes a biosimilar biological product other than an interchangeable biological product for their reference product.

The second group of commenters did not support some or all of the proposed flexibilities for biosimilar biological product substitutions to occur as immediate substitutions or maintenance changes, including interchangeable biological products. These commenters stated, for instance, that switching from biosimilar biological products to reference products was not the same as switching from generic drugs to brand name drugs and that any biosimilar biological product substitutions could disrupt patient treatment. They posited that biosimilar biological products, being complex molecules made from living organisms, are different than small molecule drugs that are chemically synthesized and that even minor differences in manufacturing processes could cause variations leading to clinical differences in a given patient's experience or reaction. They pointed out that biosimilar biological products are often used to treat patients with complex chronic conditions, whom they believe would be less well prepared to deal with adverse effects resulting from changes to the drugs they take.

The final group of commenters did not feel CMS went far enough in providing flexibilities to promote greater use of biosimilar biological products and recommended that we permit immediate substitutions of all biosimilar biological products regardless of whether they are licensed as interchangeable biological products or not. They pointed to the fact that FDA had found all biosimilar biological products to be highly similar and to have no clinically meaningful differences from reference products in safety and effectiveness and pointed out that FDA's recently proposed labeling changes would reduce the visibility of a product's interchangeability status. These commenters stated that interchangeability is only meaningful in that it allows substitution at the pharmacy counter. A commenter stated that treating biosimilar biological products other than interchangeable biological products as maintenance changes would not go far enough to make a major difference in terms of savings because the regulation would still require 30 days' advance notice, time in which the product could already have been switched. A few of these commenters acknowledged that if we did not move towards more flexibility, they supported what we had proposed.

Response: We appreciate the time all commenters took to explain many different points of view regarding biosimilar biological products, which are a relatively new category of products on the market. We appreciate the first group of commenters who supported our proposals to permit immediate substitutions of interchangeable biological products and maintenance changes of all biosimilar biological products. As explained in section III.F.2.b.(1) of the November 2023 proposed rule, our proposal accounts for the current PHSA delineation between interchangeable biological products, which may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product (also called pharmacy-level substitution), and biosimilar biological products which do not meet the standards for interchangeability. However, substitution in terms of the conditions and requirements that must be met for a pharmacist to dispense a biosimilar biological product in place of its reference product without a new prescription is subject to state pharmacy law. Our review of state requirements with respect to pharmacy-level substitutions involving biosimilar biological products indicates that currently states overwhelmingly require that a biosimilar biological product is an interchangeable biological product for a pharmacist to make such a substitution for a reference product without the intervention of the health care provider who prescribed the reference product, among other conditions and requirements.[51] [52] [53] Our goal is to promote greater use of biosimilar biological products, and for that reason we expanded our original December 2022 proposal in the November 2023 proposed rule to include as maintenance changes substitutions of biosimilar biological products other than interchangeable biological products for their reference products. Since in most cases a pharmacist would not be permitted to make a pharmacy-level substitution involving biosimilar biological products other than interchangeable biological products without the intervention of the prescriber, we maintain our decision that substitutions of biosimilar biological products other than interchangeable biological products should be maintenance changes with 30-days advance notice to provide enrollees with time to obtain new prescriptions for the biosimilar biological products other than interchangeable biological products or obtain formulary exceptions for the reference products.

We do not agree with commenters in the second group that did not support permitting any formulary changes for biosimilar biological products. We believe that the emerging biosimilars market provides too great an opportunity for potential savings and that prohibiting plan sponsors from making such formulary changes would fail to acknowledge FDA determinations that such products are as safe and effective as their reference products and could discourage greater use of biosimilar biological products.

As to the last group of commenters, we disagree that our proposals did not go far enough in providing plan sponsors with flexibilities to promote greater use of biosimilar biological products. With respect to the comment that treating formulary substitutions for reference products of biosimilar

[51] *https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf.*

[52] *https://www.mintz.com/sites/default/files/media/documents/2019-02-08/State%20Legislation%20on%20Biosimilars.pdf* n.

[53] *https://www.nacds.org/pdfs/government/2021/State-Substitution-Practices-for-Biological-Drugs-chart-July-2021.pdf.*

biological products other than interchangeable biological products as maintenance changes would not make much of a difference in savings, we note that our proposed policy is still a significant change from our current sub-regulatory policy. Current policy treats biosimilar biological product substitutions as non-maintenance changes, and exempts such biosimilar biological product substitutions from applying to enrollees currently taking an affected drug for the remainder of the plan year, which limits the potential cost savings of any such formulary change.

Comment: A commenter specifically supported our definition of ''biosimilar biological product.'' A few commenters each respectively asked that we: (i) revise the definition of ''unbranded biological product'' in our proposed § 423.4 to be modeled on the definition of ''authorized generic drug'' found in section 505(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)), which includes a description of distribution; (ii) provide an explanation of the meaning of the word ''potency'' as used in our proposed definition of a ''biosimilar biological product'' in § 423.4; and (iii) revise our definition in § 423.4 to define ''interchangeable biological product'' in order that it resemble the statutory definition in 42 U.S.C. 262(i)(3). Another commenter asked that we add biological products to the existing definition of ''brand drug'' in § 423.4 (more precisely, ''brand name drug'') to be more like our current definition of ''covered Part D drug'' in § 423.100 includes both small molecule drugs and biological products.

Response: While we appreciate the comments, we disagree with the suggestions to change our proposed definitions. Specifically, we are not revising the proposed definition of ''unbranded biological product'' to conform it to a statutory definition of ''authorized generic drug.'' Our proposed definition is consistent with how the FDA considers the unbranded biological product to be the same product as the brand name biological product, but marketed without the brand name on its label.[54] Nor do we think it is necessary for the purpose of CMS regulations to redefine what potency means for ''biosimilar biological products.''

We are persuaded to revise our proposed definition of ''interchangeable biological product'' in § 423.4 to include language that links the standards described in 42 U.S.C. 262(k)(4) to the definition of interchangeability at 42 U.S.C. 262(i)(3), since this is more descriptive while maintaining the accuracy of the proposed definition. We will therefore modify our proposed definition of ''interchangeable biological product'' in this final rule by adding the following language to the end: ''which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.''

We decline to revise our definition of brand name drug given that we are finalizing a definition of ''brand name biological product'' in § 423.4, as proposed.

Comment: Several commenters who did not agree with our policy proposals contended that CMS was undermining the work of the FDA. For instance, a commenter stated that it is the role of FDA to decide what biosimilar biological products are interchangeable. In their opinion, if CMS were to permit Part D plans to substitute any biosimilar regardless of a determination of interchangeability, this is tantamount to disregarding the distinction between interchangeable biological products and biosimilars other than interchangeable biological products as set forth in the PHSA. On the other hand, several commenters that supported our proposed policies believed our policies were consistent with those of FDA. Several commenters on all sides of the issue looked to FDA publications and studies to support their positions, with a few citing the Biologics Price Competition and Innovation Act (BPCIA) or the PHSA. A few commenters also asked CMS to work with FDA, and one commenter specifically requested that the two agencies come to a consensus on the definitions and data surrounding biosimilarity and interchangeability, and the need for any more studies to support interchangeability determinations.

Response: We disagree that our proposals interfere with FDA's review of biosimilar biological products. CMS, among other things, works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system.[55] This includes regulation of Part D sponsors. FDA's mission, among other things, is to protect the public health by assuring the safety, efficacy, and security of human drugs and biological products.[56] It has long been the case that both agencies have had overlap on some issues, and both agencies have undertaken complementary initiatives under the Executive Order on Promoting Competition in the American Economy (E.O. 14306). Examples of such initiatives include FDA's work to continue to clarify and improve the approval framework for generic drugs and biosimilar biological products to make generic drug and biosimilar biological product approval more transparent, efficient, and predictable, including improving and clarifying the standards for interchangeability of biological products, as well as CMS's efforts to prepare for Medicare and Medicaid coverage of interchangeable biological products, and to develop payment models to support increased utilization of generic drugs and biosimilar biological products. This work includes issuing regulations codifying definitions specific to our missions and authorities. The policies being finalized in this rule are appropriate for the needs of the Part D program.

Comment: A commenter questioned the underlying premise for our proposed policies, noting that, as compared to brand name drugs and generics, biosimilar biological products were not priced at a significant savings from their reference products. Another commenter stated that treating substitutions of reference products with biosimilar biological products other than interchangeable biological products as maintenance changes would not make a major difference in terms of the uptake of biosimilar biological products because it would not cause manufacturers of reference products to provide lower prices or increase rebates. Another commenter posited that providing more flexibilities for biosimilar biological products other than interchangeable biological products could dampen manufacturer innovation by reducing the incentive to devote additional time and resources to interchangeable product development.

[54] See FAQ #11: How are ''unbranded biologics'' displayed in the Purple Book? *https://purplebooksearch.fda.gov/faqs#11.*

[55] *https://www.cms.gov/about-cms#:~:text=CMS%20is%20the%20federal%20agency,in%20the%20health%20care%20system.* ''CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.''

[56] *https://www.fda.gov/about-fda/what-we-do#mission* ''The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.''

Lastly, another commenter did not support our policy on the basis that allowing Part D sponsors to remove reference products from their formularies removes incentives for the biosimilar biological product to compete on price and could harm biologic competition, especially when only one or a few biosimilar biological products are currently on the market.

Response: These comments highlight a variety of factors that may influence the biological product market, but we do not speculate on every potential downstream effect of our proposal to permit substitutions of biosimilar biological products other than interchangeable biological products as maintenance changes. It is up to Part D sponsors to negotiate with manufacturers, and section 1860D–11(i) of the Act generally prohibits the Secretary from interfering with those negotiations. We believe that it is in the interest of the Part D program and Medicare beneficiaries to provide Part D sponsors with flexibilities that can be leveraged in negotiations with manufacturers to reduce costs to the government and Medicare beneficiaries. While we cannot estimate savings for our proposals with any certainty or predict whether fewer or more manufacturers will produce interchangeable biological products in the future, we clarify that the intent of this specific proposal has never been to affect decisions by manufacturers. Rather our goal is to promote greater access to and utilization of biosimilar biological products by providing more flexibility for Part D sponsors to substitute them for reference products than had previously been permitted. The introduction of biosimilar biological products to the market is relatively recent compared to generic small molecule drugs. We believe there is a potential for savings to the Medicare Trust Fund in the long term as acceptance of biosimilar biological products grows and increased competition drives down costs.

Comment: A commenter pointed out that CMS stated in the December 2022 proposed rule at pages 79536–7 with respect to another proposal on midyear benefit changes that such midyear changes violate uniformity and integrity of bids. A few commenters pointed out that we had stated in our December 2022 proposed rule that it was not appropriate to immediately substitute biosimilar biological products other than interchangeable biological products, and one commenter noted that we indicated in the April 2018 final rule that it could cause confusion if we were to define generic drugs to include biosimilar biological products. Pointing out that nothing had changed since that time, these commenters suggested we had no support to undertake what they reviewed as a reversal in policy.

Response: The commenter failed to note that in the December 2022 proposed rule, we drew a distinction 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 tier to another). That discussion in the December 2022 proposed rule explained that section 1860D–4(b)(3)(E) of the Act contemplates that there will be midyear changes in cost sharing of individual formulary drugs. 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 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.

We do not believe our previously finalized policies are inconsistent with our proposal to permit substitution of biosimilar biological products other than interchangeable biological products as maintenance changes. In the December 2022 proposed rule, we stated that we were not permitting the immediate substitution of biosimilar biological products other than interchangeable biological products as immediate substitutions, and our proposals in the November 2023 proposed rule did not propose to permit such immediate substitutions. (See the November 2023 proposed rule at III.F.2.(b)(1) for a detailed discussion.) In our April 2018 final rule, we noted that, to avoid confusion, we were not finalizing a proposed rule regarding the similar treatment of biosimilar biological products and generic drugs for purposes of LIS cost-sharing. We do not believe a concern about avoiding confusion in 2018 with respect to the separate issue of LIS cost-sharing is relevant to the policy proposals in our December 2022 and November 2023 proposed rules that involve the same type of products but in a different context.

We do not believe that finalizing our proposals regarding formulary substitution of biosimilar biological products precludes us from revisiting these policies in the future. Of course, in such instances, as is the case anytime that we feel it necessary to revisit regulatory policy, we would carefully consider all factors and issue proposals through rulemaking subject to public comment and response.

We also note we are finalizing our proposals to provide safeguards to mitigate potential confusion, including a requirement that Part D sponsors provide 30 days' advance notice requirement for substitutions of biosimilar biological products other than interchangeable biological products.

Comment: Several commenters requested that we exempt enrollees currently taking a reference product if we finalize a policy that permits Part D sponsors to treat as maintenance changes formulary substitutions of biosimilar biological products other than interchangeable biological products for reference products.

Response: We disagree with these commenters. As noted earlier, we believe the right course of action is to treat such substitutions as maintenance changes. These commenters appeared to support the feature of our current sub-regulatory policy on non-maintenance changes that exempts enrollees currently taking an affected product for the remainder of the plan year from substitution of reference products by biosimilar biological products other than interchangeable biological products. However, the non-maintenance policy also requires Part D sponsors to obtain explicit approval of such changes from CMS. We believe that to continue to require every Part D sponsor that seeks to substitute a biosimilar biological product other than an interchangeable biological product for a reference product to wait to obtain explicit permission before making any change and to continue to exempt enrollees currently taking the reference product would be counter to the goal of promoting the utilization of biosimilar biological products. Additionally, as noted previously in this section, the 30-day advance notice timeframe affords enrollees sufficient time to change to a covered alternative drug which could include biological products; to get a refill of the reference product to be replaced; or to obtain needed prior authorization or an exception for the reference product affected by the formulary change. Affected enrollees may still be able to access the reference

product through the plan's coverage determination and exceptions process.

Comment: Many commenters opposed ''non-medical switching'' formulary changes that are based on payer mandated reasons other than strict medical necessity (such as cost and coverage reasons). They stated that permitting biosimilar biological product substitutions for enrollees who are stable on reference products would disrupt treatment and undermine the doctor-patient relationship and central role of prescribers in determining the best course of treatment, leading to poor health outcomes and exacerbating health care disparities. Several commenters opposed to the proposal noted that biosimilar biological product substitutions could disrupt patient care or result in unexpected cost sharing. One commenter suggested that rather than finalizing this proposal, CMS should focus on policies that empower physicians when partnering with their patients, such as expanded access to real-time benefit tool (RTBT) use. A few commenters asked us to require Part D sponsors to send notice of specific changes to the prescribers of affected enrollees. Several commenters also noted the importance of having a robust exceptions process.

Response: We take seriously concerns that enrollees, especially those facing health challenges, may have when they are either switched from a drug they have been stable on or told their plan will no longer cover it, including for products such as biosimilar biological products that are relatively new to the market. However, as we discussed in our December 2022 proposed rule and the November 2017 proposed rule and as contemplated under section 1860D–4(b)(3)(E) of the Act, Part D sponsors may make changes to their formularies as specified during the year. As detailed in the November 2023 proposed rule, all biosimilar biological products have been determined by FDA to be safe and effective, and we believe that, over time, biosimilar biological products will gain more acceptance, as was the case with generic drugs as substitutes for brand name drugs. For instance, the FDA has stated:

Both [biosimilar biological products and reference products] are rigorously and thoroughly evaluated by the FDA before approval. For [biosimilar biological products] to be approved by the FDA, manufacturers must show that patients taking [biosimilar biological products] do not have any new or worsening side effects as compared to people taking the [reference products].

As it does with all medication approvals, the FDA carefully reviews the data provided by manufacturers and takes several steps to ensure that all [biosimilar biologic products] meet standards for patient use. The FDA's thorough evaluation makes sure that all [biosimilar biological products] are as safe and effective as their [reference products] and meet the FDA's high standards for approval. This means [consumers] can expect the same safety and effectiveness from the [biosimilar biological product] over the course of treatment as [they] would from the original product.[57]

We are not convinced that sending notices to prescriber offices, which serve a great many patients covered by many types of insurance and receive many communications, is an effective means to address enrollee concerns. Prescribers are more likely to respond to direct requests from their patients asking for a new prescription or help supporting an exception request. We agree with the commenter who noted the importance of RTBTs to provide prescribers with drug coverage and cost-sharing information for their patients at the point of prescribing. CMS does not require prescribers to use RTBTs, but requires at § 423.160(b)(7) that Part D sponsors implement at least one RTBT capable of integrating with at least one prescriber's e-prescribing system or electronic health record. See section III.L.5. of this final rule for a discussion of our proposals to enable more widespread access to RTBTs through the adoption of a standard.

Lastly, we agree with commenters about the importance of a robust exceptions process being available to affected enrollees. Since the start of the Part D program in 2006, CMS has had such a process in place. Under the coverage determination and appeal processes described in Part 423, subpart M, Part D enrollees and their prescribers have the right to request an exception to a plan coverage rule, including an exception to the plan's tiered cost-sharing structure or formulary utilization management (UM) criteria. Part D plan sponsors are required to make coverage decisions and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. Under § 423.578, a Part D plan must grant a tiering or formulary exception request (for example, provide coverage for a non-formulary drug or an exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects. Enrollees have a statutory right to an expedited determination if the prescriber indicates that applying the standard timeframe may jeopardize the enrollee's health, and plans must issue all coverage decisions, except those seeking reimbursement only, as expeditiously as the enrollee's health condition requires. Any initial coverage request that the plan expects to deny based on a lack of medical necessity must be reviewed by a physician. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the right to request independent review. We require plans to conduct all redeterminations (first level appeals) using a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare criteria, if the initial denial was based on a lack of medical necessity. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we do require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all beneficiaries immediately receive clear, concise instructions on how to pursue their appeal rights whenever a prescription cannot be filled. For additional information on the coverage determination, appeals, and grievance process, including information about the pharmacy notice, see 42 CFR part 423, subparts M and U, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals

[57] See FDA website entitled ''Biosimilar and Interchangeable Biologics: More Treatment Choices'' at: *https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices#:~:text=Biosimilars%20are%20a%20type%20of,macular%20degeneration%2C%20and%20some%20cancers.*

Guidance.[58] We believe these requirements are comprehensive enough to address issues that might arise related to any transition from a reference product to a biosimilar biological product.

Comment: Several commenters specifically noted that requiring 30 days' notice for maintenance changes would be sufficient time for an enrollee to communicate with their health care provider to get a new prescription for a biosimilar biological product other than an interchangeable biosimilar biological product. A commenter asked if patients taking a reference product could waive their 30 days' advance notice of maintenance changes and immediately switch to a substituted biosimilar biological product. Several commenters asked CMS to extend the advance direct notice period from 30 days to either 60 or 90 days. These commenters posited that biosimilar biological products were different than other drugs and that enrollees taking these drugs were likely to be sicker or experiencing a chronic illness. They stated that enrollees taking reference products would need to schedule appointments with their providers to discuss changing treatment to a biosimilar biological product and that average wait times may exceed a month. Another commenter suggested that given the level of concern many patients who have been on the same medication have regarding biosimilar biological products with which they may not be familiar, providing a longer time period would give enrollees and their prescribers more of an opportunity to feel comfortable making the transition. A commenter that opposed permitting Part D sponsors to treat the substitution of biosimilar biological products for their reference products as maintenance changes, noted that the 30-day notice period might not provide sufficient time for an enrollee to obtain the biosimilar biological product if it is subject to risk evaluation and mitigation strategies (REMS). In such instances, FDA may require manufacturers to restrict a drug's distribution or use only to patients with prescriptions from authorized physicians or pharmacies under specified conditions via one or more ''Elements to Assure Safe Use'' (ETASU).

Response: As noted earlier, the needs of enrollees are an important priority for CMS. However, we have required advance direct notice of maintenance changes since the beginning of the Part D program and are not convinced that there is anything unique about biosimilar biological products other than interchangeable biological products that justifies a change to that longstanding policy. CMS has for some time permitted maintenance changes; since our April 2018 final rule, Part D plans have been required to provide 30 days' notice to these enrollees of changes. We are not aware of widespread complaints regarding the 30 days' advance direct notice, and do not believe it is necessary to create a special rule for individuals taking reference products subject to biosimilar biological product maintenance changes. We believe it would add unnecessary complications and set a poor precedent to establish a different time period of advance direct notice for biosimilar biological products substituted as maintenance changes (be they interchangeable or other than interchangeable) relative to other Part D drugs. We find this level of complications unmerited because, as discussed in section III.F of the November 2023 proposed rule, we trust in FDA evaluations that have determined all biosimilar biological products are safe and effective. See our discussion in the proposed rule for more on this (88 FR 78518). Additionally, affected enrollees may still be able to access the reference product through the plan's coverage determination and exceptions process.

Section 1860D–4(b)(3)(E) of the Act requires ''appropriate notice'' of formulary changes; further, we view appropriate notice of change as an integral beneficiary right. Therefore, we disagree that we need to change the requirement for advance direct notice of maintenance changes or create more complexity by requiring plans to create a means for enrollees to waive formulary change notice on an individual basis. If a prescriber were to recommend a switch to a new biosimilar biological product to their patient, either they or the patient could call or otherwise reach out to the plan to see if the drug was available on the formulary ahead of receipt of any 30-day advance notice of drug change.

We appreciate that a REMS could cause complications relative to the 30-day notice period, for example, if the prescriber needs to enroll in a different REMS for a biosimilar biological product than for the reference product in order to be certified to prescribe the biosimilar biological product; however, we do not think this scenario is unique to biological products. The same scenario could occur under our current policy for maintenance changes involving generic substitutions for brand name drugs, because when a brand name drug has a REMS, the generic drug must also have a REMS and manufacturers may not have a shared system REMS.[59] We are not aware of complaints indicating that our current policy for substitutions of generic drugs for brand name drugs has been complicated by REMS for drugs involved. Consequently, we do not see a need to change the policies we have proposed for substitution of biosimilar biological products.

Comment: A few commenters suggested that if we were to permit plans to require patients stable on reference products to switch to biosimilar biological products to reduce costs for payers, those savings should be shared with enrollees. A few commenters requested that we require biosimilar biological products to be placed on lower cost-sharing tiers than the reference products they replaced.

Response: By encouraging Part D sponsors to introduce biosimilar biological products to their formularies more quickly, we believe enrollees may also be able to share in savings when negotiated prices for those products are lower than for the reference products, particularly in coinsurance-based benefit designs. CMS disagrees with the commenters' proposal to require biosimilar biological products to be placed on lower cost-sharing tiers than the reference products they replaced because it has been longstanding policy to require substitutions to apply to the same or lower tier. Moreover, most biological products qualify for the specialty tier, as defined at § 423.560. Unless the plan benefit structure includes two specialty tiers as permitted under § 423.104(d)(2)(iv)(D), requiring substituted biosimilar biological products to be placed on a lower tier than the reference product would in effect prohibit Part D sponsors from placing biosimilar biological products on the specialty tier if the reference product had been on the specialty tier.

Comment: While we received support for recognizing the role of education to advance uptake and acceptance of biological products, several commenters stressed that biosimilar biological products are a relatively new concept that could cause confusion and concern for enrollees who would prefer to continue taking drugs they are familiar with. They asked that we develop educational resources on biological products to better inform patients and

[58] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

[59] *https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.*

health care professionals and urge plan sponsors to engage in robust education and utilize communications best practices. A commenter encouraged us to update the Medicare Plan Finder tool to identify coverage of and savings associated with biosimilar biological products.

Response: We plan to update our materials to reflect any regulatory changes regarding the provision of biosimilar biological products, as well as investigate options for identifying biosimilar biological product alternatives on Medicare Plan Finder. Likewise, we encourage Part D sponsors to educate their enrollees, including making sure that call center customer service representatives are trained to discuss biosimilar biological products. We note that the FDA also plays an important role in educating consumers on emerging drug therapies. FDA offers a variety of materials in multiple formats and languages to help promote understanding of biosimilar biological products and interchangeable biological products.[60]

Comment: A commenter asked us to ensure enrollees receive appropriate notifications of midyear changes, develop such notices with stakeholder feedback, and hold Part D sponsors responsible if timelines or other standards are not met. A commenter requested that if the rule is finalized, that we monitor enrollee and prescriber experiences with biosimilar biological products to determine whether notice is necessary, particularly as state laws regarding substitution evolve.

Response: We will keep this feedback in mind as we consider different monitoring options.

Comment: A few commenters were concerned that permitting immediate substitutions of interchangeable biological products for reference products and maintenance changes of all biosimilar biological products for reference products would impose a greater administrative burden upon pharmacists.

Response: While we certainly favor reducing unnecessary burdens on pharmacists, it is not clear to us how permitting immediate substitutions of interchangeable biological products under proposed § 423.120(e)(2)(i) will increase the administrative burden placed on pharmacists. State laws determine the requirements for pharmacists to make pharmacy-level substitutions of interchangeable biological products for their reference products and these pharmacy-level substitutions can take place even when a reference product remains on the formulary (that is, in the absence of any immediate substitution by the plan). We acknowledge that permitting Part D sponsors to substitute biosimilar biological products for reference products as maintenance changes means the claim will potentially be denied at the pharmacy (if the negative formulary change adds restrictions or removes the reference product from the formulary) or the enrollee will be faced with higher than expected cost-sharing (if the negative formulary change moves the reference product to a different cost-sharing tier). The changes may cause enrollees to ask the pharmacist questions at the point of sale. In some cases, a pharmacist might reach out to the patient or their prescriber to obtain a new prescription if, for example, a refill of a reference product that a patient has been taking is denied by the plan. However, the advance direct notice provided to affected enrollees is intended to prompt the enrollee to act before the formulary change takes place and before the next fill of the reference product at the pharmacy. We decline to make further changes to our proposal based on these comments.

Comment: A commenter was concerned that expanding immediate substitutions to include substitutions of authorized generics, interchangeable biological products, and unbranded biological products, as proposed in the December 2022 proposed rule, would allow plans to choose different specified products for coverage, such that facilities would have to stock every single product option or substitution, whereas currently, only one substitution needs to be stocked. Conversely, a few commenters were concerned that substituted drugs would have a different delivery form. A commenter on the November 2023 proposed rule shared concerns that, given that all biosimilar biological products are not necessarily available in all delivery forms, our proposed rule could mean enrollees would lose access to their current delivery form (for instance, be able to only obtain a vial when they currently use a pen cartridge).

Response: We appreciate the concern the commenter raised about the potential impact of our proposed policies on pharmacies that may need to stock multiple biosimilar biological products and the challenges that could create as more biosimilar biological products come to the market. However, that issue is not specific to Part D and is beyond the scope of our proposal to expand midyear substitutions. Regarding the concerns about changes in available delivery forms, under proposed § 423.120(e)(2)(i), we would only allow immediate substitutions of an interchangeable biological product that FDA has determined to be interchangeable with its reference product. Our annual formulary review process ensures that Part D plan formularies include adequate representation of drugs consistent with best practices of formularies currently in widespread use. Part D sponsors are not required to cover every dosage or delivery form of a particular drug; however, Part D sponsors are expected to cover widely available dosage and delivery forms so as to not unduly limit enrollee access. If a Part D sponsor has multiple dosage or delivery forms of a particular drug on their formulary, Part D sponsors implementing immediate substitutions will be expected to continue to offer a similar variety of dosage and delivery forms to meet the needs of patients. CMS will review changes submitted on the HPMS formulary file and take action as appropriate if it appears that any immediate substitutions are inappropriate. As for maintenance changes defined in § 423.100, these determinations are subject to our review on a case-by-case basis. CMS takes into consideration differences in available delivery forms when making decisions to approve or deny such negative change requests.

Comment: A few commenters opined that our policy conflates pharmacy substitutions and formulary coverage, and that there is a distinction between the ability of a pharmacist to substitute a product without prescriber intervention and a plan's decisions regarding formulary coverage of a product.

Response: We understand the decision by a Part D sponsor to provide formulary coverage of any given product is very different from the ability of a pharmacist to substitute a product for another drug. However, coverage decisions do not take place in a vacuum, and CMS cannot ignore practical realities despite these commenters' position that formulary design should not be affected by pharmacy substitutions policies. In contrast, CMS believes that to prevent enrollees from standing in line at the pharmacy counter unable to get the biosimilar biological product because they do not have a new prescription for it, our proposal to require 30 days' advance direct notice in § 423.120(f)(1) is appropriate.

Comment: A few commenters asked us to align our proposed regulations

[60] See the following FDA website on Multimedia Education Materials | Biosimilars: *https://www.fda.gov/drugs/biosimilars/multimedia-education-materials-biosimilars.*

with policies in certain other countries. Specifically, both a commenter that asked us to restrict immediate substitutions to interchangeable biological products and a few commenters that asked us to permit immediate substitutions of all biosimilar biological products for reference products cited policies in Europe to support their different views.

Response: We appreciate the comments but clarify that we are proposing policies on approval and notice of formulary changes for Part D plans in the United States independent of policies in other countries. As explained in detail in both the December 2022 and the November 2023 proposed rules, our policies are informed by another federal agency, FDA, which implements the statutory and regulatory framework for the review and approval of biosimilar biological products.

After consideration of the comments received on both the December 2022 and November 2023 proposals, and for the reasons set forth in the proposed rules and our responses to the comments in this final rule, we are finalizing the proposed regulation text changes at §§ 423.4, 423.100, 423.104, 423.120, and 423.128, with the minor modifications discussed below, in addition to other non-substantive organizational and editorial changes for clarity.

- In § 423.4, removing the word ''biological'' from the term ''reference biological product.''
- In § 423.4, adding the following language to the end of the definition of ''interchangeable biological product'': ''which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.''
- In § 423.100, in the definition of ''maintenance change,'' revising and reordering language to provide more clarity by stating that drugs subject to removal include those ''that FDA determines to be withdrawn for safety or effectiveness reasons.''
- In § 423.120(b)(5), finalizing the requirement that Part D sponsors must provide notice of changes as specified in § 423.120(f), but removing a reference to selection of a successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D–4(b)(3)(I)(ii) of the Act.
- In § 423.120(e)(2)(ii), revising and reordering language on market withdrawals to provide more clarity by stating that drugs subject to removal include those ''that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.''
- In § 423.120(f)(4)(iv), revising language requiring Part D sponsors to include in their written notice of change a list of formulary alternatives to specify that the alternative drugs be ''on the formulary'' to make clear these alternatives are on the formulary and can meet the definition of a Part D drug.
- In § 423.120(f)(4)(v), revising language specifying that Part D sponsors provide written notice of the coverage determinations and exceptions to make clear that an exception is a type of coverage determination and to correct the regulatory cross-reference.

Additionally, in the course of developing the final rule, it came to our attention that we had inadvertently omitted updating § 423.578(d) when proposing updates to the regulations to reflect the agency's proposals. Accordingly, we are making conforming changes in this final rule to the existing regulation text in § 423.578(d) to correspond with the changes we are finalizing in this rule to require Part D sponsors to provide notice regarding negative formulary changes under § 423.120(f).

O. Parallel Marketing and Enrollment Sanctions Following a Contract Termination (§§ 422.510(e) and 423.509(f))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide CMS with the ability to terminate MA (including MA–PD) and PDP contracts if we determine that a contract(s) has met any of the following thresholds:

- Has failed substantially to carry out the contract
- Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of, respectively, Part C or Part D of Title XVIII of the Act (that is, the Medicare statute).
- No longer substantially meets the applicable conditions of the applicable part of the statute.

This termination authority is codified at 42 CFR 422.510(a)(1) through (3) and 423.509(a)(1) through (3), respectively. In addition, section 1857(g)(3) of the Act (incorporated for Part D sponsors under section 1860D–12(b)(3)(F) of the Act) specifies that intermediate sanctions and civil money penalties (CMPs) can be imposed on the same grounds upon which a contract could be terminated (63 FR 34968 and 70 FR 4193). CMS codified this authority at §§ 422.752(b) and 423.752(b) with respect to intermediate sanctions, and §§ 422.752(c)(1)(i) and 423.752(c)(1)(i) with respect to CMPs.

If CMS terminates an MA organization or Part D sponsor contract(s) during the plan year but the termination is not effective until January 1 of the following year, the MA organization or Part D sponsor could potentially continue to market and enroll eligible beneficiaries (as described in 422 Subpart B and 423 Subpart B) into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s).[61] A terminating contract that continues to market to and enroll eligible beneficiaries will cause confusion and disruption for beneficiaries who enroll in the period of time between when the termination action is taken and the January 1 effective date of the termination.

For these reasons, we proposed to add paragraph (e) to § 422.510 and paragraph (f) to § 423.509 that, effective contract year 2025, marketing and enrollment sanctions will automatically take effect after a termination is imposed. At paragraph (e)(1) of § 422.510 and paragraph (f)(1) of § 423.509, we proposed to state that the marketing and enrollment sanctions will go into effect 15 days after CMS issues a contract termination notice. This timeframe is consistent with the number of days CMS often designates as the effective date for sanctions after CMS issues a sanction notice.

At paragraph (e)(2) of § 422.510 and paragraph (f)(2) of § 423.509, we proposed that MA organizations and Part D sponsors will continue to be afforded the same appeals rights and procedures specific to contract terminations under 42 CFR Subpart N of parts 422 and 423, however, there will not be a separate appeal for the sanction (in other words the appeal of the termination will include the associated marketing and enrollment sanctions). In addition, at paragraph (e)(3) of § 422.510 and paragraph (f)(3) of § 423.509 we proposed that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions will not be stayed pending the appeal consistent with §§ 422.756(b)(3) and 423.756(b)(3). Finally, at paragraph (e)(4) of § 422.510 and paragraph (f)(4) of § 423.509 we proposed that the sanction will remain in effect until the effective date of the termination, or if the termination decision is overturned on appeal, until

[61] Regulations in 42 CFR 422 Subpart B and 423 Subpart B permit enrollees to enroll in a plan mid-year during their initial election period or special election periods.

the final decision to overturn the termination is made by the hearing officer or Administrator.

CMS rarely terminates MA organization and Part D sponsor contracts and, on average, contract terminations affect less than one MA organization or Part D sponsor a year. Therefore, we anticipate that this proposal will not result in additional costs or additional administrative burden for affected MA organizations and Part D sponsors. For example, an MA organization and Part D sponsor will not be required to submit a corrective action plan, and if appealed there will only be one appeal rather than multiple. MA organizations and Part D sponsors will continue to be required to comply with existing regulations that require public and beneficiary notice that their contract is being terminated under this proposal.

Comment: Several commenters expressed support for this proposal.

Response: CMS appreciates commenters' support.

Final Decision: After consideration of the public comments received and for the reasons discussed here and in the proposed rule, we are finalizing this provision without modification.

P. Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

Individuals with limited English proficiency (LEP) experience obstacles to accessing health care in the United States. Language barriers negatively affect the ability of patients with LEP to comprehend their diagnoses and understand medical instructions when they are delivered in English and impact their comfort with post-discharge care regimens.[62] We further described the language barriers faced by individuals with LEP in the November 2023 proposed rule at 88 FR 78523. These barriers contribute to disparities in health outcomes for individuals with LEP, which likely worsened during the COVID–19 pandemic.[63]

The multi-language insert (MLI) currently required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These were the 15 most common non-English languages in the United States when we reinstituted the MLI in the 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 final rule (87 FR 27704) (hereafter referred to as the May 2022 final rule). Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the five percent threshold, where it determines that including the language would be appropriate. The current MLI states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' The issuance of the MLI is independent of the Medicare written translation requirements for any non-English language that meets the five percent threshold, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2), and the additional written translation requirements for fully integrated D–SNPs (FIDE SNPs) and highly integrated D–SNPs (HIDE SNPs) provided in §§ 422.2267(a)(4) and 423.3367(a)(4).[64] Additionally, we note that pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, we have also established in § 417.428 that most of the marketing and communication regulations in subpart V of part 422, including the MLI requirement in § 422.2267(e)(31), also apply to section 1876 cost plans.

Section 1557 of the Patient Protection and Affordable Care Act (ACA)[65] provides that, except where otherwise provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, *42 U.S.C. 2000d et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, *20 U.S.C. 1681 et seq.* (sex), the Age Discrimination Act of 1975, *42 U.S.C. 6101 et seq.* (age), or section 504 of the Rehabilitation Act of 1973, *29 U.S.C. 794* (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance); any program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (*81 FR 31375;* hereinafter referenced to as the ''2016 section 1557 final rule'') implementing the requirement that all covered entities—any health program or activity that receives Federal financial assistance—include taglines with all ''significant communications.'' The sample tagline provided by the Department consisted of a sentence stating, in the 15 most common non-English languages in a State or States, ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).'' On June 19, 2020, the Department published a new section 1557 final rule, 85 FR 37160 (2020 section 1557 final rule), rescinding the 2016 section 1557 final rule's tagline requirements, 84 FR 27860. That rule is currently in effect, save for a few provisions enjoined or set aside by the courts and pending OCR's new proposed rule for section 1557 of the ACA, published on August 4, 2022 (87 FR 47824).

None of the rulemaking impacting the various notifications of interpreter services changed the requirement that MA organizations, Part D sponsors, or cost plans must provide these services under applicable law. Plans have long been required to provide interpreters when necessary to ensure meaningful access to individuals with LEP, consistent with existing civil rights laws. In implementing and carrying out the Part C and D programs under

[62] Espinoza, J. and Derrington, S. ''*How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?*'', *AMA Journal of Ethics* (February 2021) E109. Retrieved from *https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-02/cscm3-2102.pdf;* Karliner, L., Perez-Stable, and E., Gregorich, S. ''*Convenient Access to Professional Interpreters in the Hospital Decreases Readmission Rates and Estimated Hospital Expenditures for Patients with Limited English Proficiency*'', *Med Care* (March 2017) 199–206. Retrieved from *https://pubmed.ncbi.nlm.nih.gov/27579909/.*

[63] Lala Tanmoy Das et al., Addressing Barriers to Care for Patients with Limited English Proficiency During the COVID–19 Pandemic, Health Affairs Blog (July 29, 2020), *https://www.healthaffairs.org/do/10.1377/hblog20200724.76821/full/.*

[64] This proposal pertains only to the MLI requirements in §§ 422.2267(e)(31) and 423.2267(e)(33), not §§ 422.2267 and 423.2267 broadly.

[65] 42 U.S.C 18116(c).

sections 1851(h), 1852(c), 1860–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, 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 LEP are aware of and are able to access interpreter services provides a clear path for this portion of the population to properly understand and access their benefits.

In the May 2022 final rule, we noted that we gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries (87 FR 27821). We stated that we consider the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary's decision-making process. We also noted that we reviewed complaint tracking module (CTM) cases in the Health Plan Management System (HPMS) related to ''language'' and found a pattern of beneficiary confusion stemming from not fully understanding materials based on a language barrier. We noted that solely relying on the requirements delineated in the 2020 section 1557 final rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans. We stated that we believed that informing Medicare beneficiaries that interpreter services are available is essential to realizing the value of our regulatory requirements for interpreter services.

On August 4, 2022, OCR published a new proposed rule for section 1557 of the ACA (87 FR 47824) that proposed to require covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities at no cost using a notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). Proposed 45 CFR 92.11(b) would require the Notice of Availability to be provided in English and at least in the 15 most common languages spoken by individuals with LEP in the relevant State or States, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. These proposed provisions would result in misalignment with the MLI requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) which require that notice be provided in the 15 most common non-English languages in the United States.

In addition, under § 438.10(d)(2), States must require Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management programs to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State explaining the availability of oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services in the State. Several States that use integrated Medicare and Medicaid materials for D–SNPs and Medicare-Medicaid Plans have contacted CMS and requested that we change the MLI to be based on the 15 most common languages in the State rather than the 15 most common languages nationally because the most common languages in the State are often not the same as the most common 15 languages nationally.

As a result of the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2), any applicable integrated plans (AIPs), as defined at § 422.561, that provide integrated Medicare and Medicaid materials for enrollees must currently include the MLI in the 15 most common languages nationally as well as the Medicaid tagline in the prevalent non-English languages in the State to comply with both Medicare and Medicaid regulatory requirements. Specifically, these plans that provide integrated materials must comply with the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2) to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State. In the enrollee materials, this can result in a very long multi-page list of statements noting the availability of translations services in many languages. As discussed in greater detail below, we proposed to update §§ 422.2267(e)(31) and 423.2267(e)(33) to instead require that a Notice of Availability be provided in English and at least the 15 languages most commonly spoken by individuals with LEP of the relevant State; we articulated our expectation that this proposed policy would better align with the Medicaid translation requirements at § 438.10(d)(2).[66]

We believe rulemaking regarding a notice of the availability of language assistance services and auxiliary aids and services for individuals with LEP is needed to more closely reflect the actual languages spoken in the service area. We also believe it is in the best interest of enrollees for the requirements to align with the Medicaid translation requirements because it allows D–SNPs that are AIPs to provide a more applicable, concise Notice of Availability to enrollees that does not distract from the main purpose of the document. Further, alignment of Medicare and OCR rules would help to prevent confusion among MA organizations, Part D sponsors, and cost plans regarding which requirements they must comply with.

We proposed to amend §§ 422.2267(e)(31) and 423.2267(e)(33). First, we proposed to replace references to the MLI with references to a Notice of Availability. We proposed that this notice be a model communication material rather than a standardized communication material and thus that CMS would no longer specify the exact text that must be used in the required notice. Second, we proposed to change paragraphs (e)(31) and (e)(33) to require MA organizations and Part D sponsors to provide enrollees a Notice of Availability that, at a minimum, states that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge. Third, we proposed, in new paragraphs (e)(31)(i) and (e)(33)(i), that the Notice of Availability must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. We noted in the proposed rule that this State-specific standard would ensure that a significant proportion of each State's particular LEP population receives key information in the appropriate languages. We cited the U.S. Census Bureau's ACS 2009–2013 multi-year data, which show that the top languages spoken in each State can

[66] We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our NPRM would reduce burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

vary significantly.[67] We concluded that State-specific language translations provide for flexibility to maximize access to care for individuals with LEP. Fourth, we proposed that the updated notice must also include a statement regarding the availability of appropriate auxiliary aids and services to reduce barriers to access for individuals with disabilities.

As discussed in the November 2023 proposed rule, we believe this proposal would make it easier for individuals 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. Additional benefits include mitigating the risk that §§ 422.2267(e)(31) and 423.2267(e)(33) could conflict with § 438.10(d)(2) and the forthcoming 1557 final rule, requiring applicable Medicare plans to comply with two, disparate sets of requirements. Further, requiring MA organizations and Part D sponsors to provide multiple sets of translated statements accompanying enrollee materials could lead to enrollee confusion and detract from the enrollee material message. Setting aside which specific policies are finalized in the forthcoming 1557 final rule, we generally continue to believe our proposed changes are appropriate given the benefits of a Notice of Availability for individuals with LEP and auxiliary aid and service needs more closely reflecting the actual languages spoken in the service area and aligning with the Medicaid translation requirements.

Additionally, we proposed in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) that if there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph §§ 422.2267(a)(2) and 423.2267(a)(2), beyond the languages described in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i), the Notice of Availability must also be translated into those languages, similar to the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). While §§ 422.2267(a)(2) and 423.2267(a)(2) apply to the Notice of Availability since it is a required material under §§ 422.2267(e) and 423.2267(e), we wanted to clarify this in the regulation text. MA organizations and Part D sponsors may also opt to translate the Notice of Availability in any additional languages that do not meet the 5 percent service area threshold at §§ 422.2267(a)(2) and 423.2267(a)(2), where the MA organization or Part D sponsor determines that such inclusion would be appropriate, which is also included in the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). It is possible that there may be a subpopulation in the plan benefit package service area that uses a language that does not fall within the top 15 non-English languages or meet the 5 percent service area threshold that the plan determines can benefit by receiving the notice. We noted that pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, and as established in § 417.428, this proposal would also apply to section 1876 cost plans.

To assist plans with fulfilling their requirements under §§ 422.2267(a)(2) and 423.2267(a)(2) to translate required materials into any non-English language that is the primary language of at least five percent of the population of a plan service area, since 2009 CMS has provided plans with a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S. Each fall, we release an HPMS memorandum announcing that MA organizations and Part D sponsors can access this list in the HPMS marketing review module.[68] However, plans can also use U.S. Census Bureau ACS data to determine the top languages spoken in a given State or service area. The September 2023 Medicare Part C & D Language Data Technical Notes[69] outlines our methodology for calculating the percentage of the population in a plan's service area speaking a language other than English and provides plans with instructions to make these calculations on their own.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters supported CMS's plan to require MA and Part D plans to provide enrollees a Notice of Availability that, at a minimum, states that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge in English and at least the 15 languages most commonly spoken by individuals with LEP of the relevant State and languages that meet the 5 percent service area threshold. The Medicaid and CHIP Payment and Access Commission (MACPAC) noted that the change aligns with work they have underway, more closely aligns Medicare requirements with existing Medicaid standards, reduces administrative burden on health plans, and may reduce health disparities for beneficiaries whose primary language is not English. A commenter stated that integrated Medicare and Medicaid plans have been experiencing this conflict between Medicaid requirements and Medicare MLI requirements for many years. Another commenter stated that using the same standard as Medicaid will reduce administrative time and effort for State Medicaid agencies overseeing D–SNPs by enabling State Medicaid staff to enforce a standard consistent with their other Medicaid products.

Response: We appreciate the widespread support for our proposal. We believe that requiring a Notice of Availability to be provided in English and in at least the 15 most commonly spoken non-English languages and languages that meet the 5 percent service area threshold free of charge is more closely tailored to the needs of the population where the notice will be sent and will make it easier for individuals to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through a D–SNP, where applicable), increasing their ability to make informed health care decisions. It will also promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care.

Comment: A few commenters opposed the proposal noting that it would place an undue administrative burden on plans, including national subcontractors that work with multiple plans across multiple States. Some commenters raised concerns about providing a State-based notice for plans with multi-State service areas. A commenter stated that providing the Notice of Availability based on an

[67] *https://www2.census.gov/library/data/tables/2008/demo/language-use/2009-2013-acs-lang-tables-nation.xls.*

[68] We released the contract year 2024 version of this HPMS memorandum titled, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis'' on September 25, 2023. This memorandum can be retrieved at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

[69] Found in HPMS as described in the September 25, 2023 HPMS memo, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis.'' This memo can be retrieved at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

enrollee's location would require plans to implement enrollee-level programming for every plan communication for all 50 States. A few commenters reported having employer-group waiver plans that covered more than one State.

Response: We thank the commenters for their thoughts. We believe that requiring the Notice of Availability to be provided in at least the 15 most common languages spoken by individuals with LEP where the notice will be sent will make it easier for individuals 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. Any subcontractors will need to work with the applicable plan to ensure that they are meeting this requirement.

However, we share the concerns raised by commenters about plans that have a service area covering multiple States and the potential burden associated with determining the State of residence for enrollees within the plan. We also agree that requiring such plans to include the Notice of Availability in at least the top 15 non-English languages in each State in the plan's service area, potentially resulting in many more than 15 languages, may cause enrollee confusion and undue administrative and financial burden to the plan. As a result, we are updating the regulation to require the Notice of Availability to be provided in at least the top 15 languages most commonly spoken by individuals with LEP within the State or States associated with the plan benefit package service area, consistent with the section 1557 proposed rule. This approach would allow plans to aggregate the populations with LEP across all States in the plan's service area to determine the 15 languages in which it must provide the Notice of Availability. For example, if a plan's service area is New York, the Notice of Availability must include at least the top 15 languages spoken by individuals with LEP in New York, based on guidance published by the Secretary. If the plan's service area includes Connecticut, New Jersey, and New York, the plan may aggregate the populations with LEP across Connecticut, New Jersey, and New York to determine the 15 languages in which it must provide the Notice of Availability, based on guidance published by the Secretary. If the service area does not include an entire State, the plans should still use the top 15 languages for the entire State. If the service area is national, the plan may use the top 15 languages nationally for the Notice of Availability, based on guidance published by the Secretary.

Comment: Another commenter questioned whether, if CMS finalizes the proposal as a model communication material, plans can use each State's required tagline and language for the Notice of Availability.

Response: Since D–SNPs are State-specific at the plan level this will still allow D–SNPs to comply with § 438.10(d)(2) and use the State-specific tagline to satisfy the Notice of Availability requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) as long as it states, at a minimum, in at least the 15 most common non-English languages and any language that meets the 5 percent service area threshold, that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge, since the Notice of Availability does not require standardized language. The D–SNP will not need to include multiple notices to meet these Medicaid and Medicare regulatory requirements.

Comment: A few commenters requested that we publish annually the 15 most common languages spoken by individuals with LEP in each State and nationally. Other commenters requested that we expand the list beyond 15 languages such as to the top 20 languages most commonly spoken by individuals with LEP in each State. They stated that including the top 20 languages on the list would help advocates identify languages that may meet the plan coverage area threshold even if they are not on the list of the top 15 for the State.

Response: We appreciate commenters' requests for CMS to publish lists of the top languages in each State and note that HHS will provide a list of the top 15 non-English languages most commonly spoken by individuals with LEP in each State and nationally based on the U.S. Census Bureau's American Community Survey (ACS) data. Additionally, since 2009, CMS has provided plans with a list of all languages that are spoken by five percent or more of the population for every county in the U.S. Each fall, we release an HPMS memorandum announcing that MA organizations and Part D sponsors can access this list in the HPMS marketing review module.[70] Further, the HPMS memorandum notes that plans can also use U.S. Census Bureau ACS data to determine the top languages spoken by individuals with LEP in a given State or service area. The September 2023 Medicare Part C & D Language Data Technical Notes[71] outlines our methodology for calculating the percentage of the population in a plan's service area speaking a language other than English and provides plans with instructions to make these calculations on their own.

We also appreciate commenters asking us to publish more than the 15 top languages spoken by individuals with LEP in each State. Plans will be able to identify the top 15 languages most commonly spoken by individuals with LEP in any State based on guidance published by the Secretary. Plans may opt to include additional languages, for which the U.S. Census Bureau's ACS data would be a helpful data source. We will consider expanding the list of languages provided in HPMS for MA and Part D plans in a future HPMS update.

Comment: A few commenters requested that we provide our methodology for determining the top 15 languages spoken by individuals with LEP in a State.

Response: We will provide guidance explaining our methodology for determining the top 15 languages spoken by individuals with LEP in each State and nationally based on ACS data.

Comment: A commenter encouraged CMS to clarify that the languages available be based on the ''plan State'' and not the enrollee's State of residence.

Response: We clarify that the requirement is based on the State or States associated with the plan benefit package service area rather than where an organization is located. To improve clarity, we are updating the regulation text at §§ 422.2267(e)(31) and 423.2267(e)(33) to, ''State or States associated with the plan's service area.''

Comment: We received a few comments asking us to clarify which communications a Notice of Availability must accompany and the frequency with which the Notice of Availability is sent to enrollees. A commenter suggested we develop a targeted list of

[70] We released the contract year 2024 version of this HPMS memorandum titled, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis'' on September 25, 2023. This memorandum can be retrieved at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

[71] Found in HPMS as described in the September 25, 2023 HPMS memo, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis.'' This memo can be retrieved at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

materials with which to include the Notice of Availability while another commenter requested that we limit the types of documents that a Notice of Availability must accompany to those documents sent less frequently. Another commenter urged that we make the Notice of Availability an annual mailing instead of requiring inclusion in all materials and allow it to be suppressed if an enrollee has indicated a language of preference.

Response: While we acknowledge the comments suggesting we reduce the frequency with which we require the Notice of Availability, we believe it is important to continually make enrollees aware of the availability of language assistance services in all required materials under §§ 422.2267(e) and 423.2267(e). The requirement to include notice of available interpreter services and auxiliary aids and services with all required materials is an established policy that is already provided for in CMS regulations. CMS did not propose any amendments to this aspect of its policy as enrollee language and format preferences and needs may change over time. We also note that §§ 422.2267(e)(31) and 423.2267(e)(33) include provisions, such as allowing for a single copy of the requisite notice to be included in a mailing of multiple required documents, that ease burden and offer plans some flexibility, where practicable.

Comment: Several commenters requested that we work with OCR and Medicaid to ensure consistency between our proposal, the OCR section 1557 final rule, and Medicaid regulations.

Response: We thank the commenters recommending we better align our regulations with other relevant regulations. We strive to achieve this goal by better aligning Medicare regulations at 42 CFR 422.2267(a)(2) and 423.2267(a)(2) with OCR regulations at 45 CFR 92.11 and Medicaid regulations at 42 CFR 438.10(d)(2). We note that we have continued to work closely with OCR, the CMS Center for Consumer Information and Insurance Oversight (CCIIO), and other offices throughout the drafting of our rule to ensure alignment of regulations and mitigate burden on plans.

Comment: Several commenters opposed the use of a model notice instead of standardized language for the Notice of Availability. However, another commenter specifically noted support for the model communication approach and urged CMS to routinely review plans' Notices of Availability for compliance. A commenter requested that we work with States to publish a national Notice of Availability and any associated disclaimers, which aligns with all State requirements and accommodates all multi-plan materials by June of every year to reduce complexity and prevent enrollee confusion. Another commenter asked that we use specific notice language to ensure that all enrollees receive a full explanation of their rights while another commenter expressed concern that a model notice may result in more errors. Finally, another commenter recommended we collaborate with relevant stakeholders to develop a single, uniform Notice of Availability that can be used by health plans and providers without customization in the top 31 languages spoken nationally to accommodate 99 percent of the LEP population.

Response: We appreciate the commenters' concerns that a model Notice of Availability rather than standardized language may result in more errors and the concern with ensuring enrollees receive a full explanation of their rights. We also appreciate the support in making the Notice of Availability a model communication.

To mitigate errors in messaging, we specified that the content of the Notice of Availability must include at minimum, a statement that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge. In addition, for the purpose of compliance with section 1557 of the Affordable Care Act, OCR will be providing model language translated into the 15 languages most commonly spoken by individuals with LEP in every State and nationally that plans can use as a template to comply with the proposed CMS notice requirements. Also, allowing the use of a model Notice of Availability provides flexibility for D–SNPs in States that may require the use of a specific tagline or Notice language so that they do not have to include additional language in materials. We believe that allowing this flexibility along with the OCR model language outweighs the risk of errors in messaging.

We also thank the commenter for the recommendation to develop a Notice of Availability list translated in the top 31 languages spoken nationally. However, we believe that a list of 31 languages would be too long. As we explained in the proposed rule (88 FR 78525), States with AIP D–SNPs contacted CMS concerned that compliance with Medicaid requirements at § 438.10(d)(2) and Medicare requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) would require D–SNPs to include a Notice with a long list of languages in the required materials. One State described how their current list of languages to comply with Medicare and Medicaid requirements for D–SNPs was over four pages. We noted this as a reason for updating this regulation in the proposed rule. As the commenter points out, lengthy notices can dilute the primary message, making it more difficult for enrollees to receive critical information. Lengthy inserts can also increase costs for plans.

Comment: A commenter encouraged us to promote flexibility for plans to send materials digitally as nearly a quarter of the commenter's plan enrollees selected to receive plan materials electronically. The commenter suggested we require MA organizations to ask enrollees for email address and cell phone information as part of the enrollment application.

Response: We clarify that plans may send the Notice of Availability digitally with required materials as described and permitted in proposed §§ 422.2267(e)(31)(vii) and 423.2267(e)(33)(vii) which we have renumbered as §§ 422.2267(e)(31)(ii)(G) and 423.2267(e)(33)(ii)(G) in this final rule that the notice may be provided electronically when a required material is provided electronically as permitted under §§ 422.2267(d)(2) and 423.2267(d)(2). We also note that the model MA enrollment form includes a section where enrollees can note materials they would like to receive via email and the option to add their email address. Enrollees may also include their cell phone number in the application.

Comment: A commenter questioned if the reference to ''auxiliary aids'' in the CMS proposal equates to what CMS traditionally considered alternate formats: audio, large print, and braille. Another commenter requested that braille be exempt from the requirement because plans know that an enrollee's preference is braille if the enrollee is already receiving documents in braille.

Response: We thank the commenter for the question and clarify that, in alignment with OCR, we define ''auxiliary aids'' as written in 45 CFR 92.102.[72] As noted, plans must provide the Notice of Availability in alternate formats, if requested. If an enrollee indicates a preference for receiving materials in braille, the plan should also provide that enrollee with the Notice of Availability text in English braille, and then—not in braille—include the text in the 15 languages most commonly

[72] *https://www.ecfr.gov/current/title-45/section-92.102.*

spoken by individuals with LEP in the State or States associated with the plan benefit package service area, informing them of the availability of verbal translation services as well as alternate formats. If an enrollee requests materials in large print, then the plan should provide them with the Notice of Availability text in English in large print and in at least the 15 languages most commonly spoken by individuals with LEP in the State or States associated with the plan benefit package service area. Plans must also comply with section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act, which may include providing the Notice of Availability in an alternate format or providing another auxiliary aid or service such as braille. Thus, if an enrollee is in need of the Notice of Availability in an alternate format or through another auxiliary aid or service, the enrollee's plan would likely already be required to provide the Notice of Availability in the requested medium, to comply with section 504 and section 1557.

Comment: Some commenters recommended that we delay the effective date or enforcement of the requirement to CY 2026 or until OCR's final rule is released to ensure consistency and prevent what they characterize as undue burden to plans. A commenter stated a concern with being able to include the associated costs in their 2024 MA bids and the time required to make the administrative updates.

Response: We appreciate the commenters' concerns about the timing of our proposal and OCR's section 1557 final rule. We have worked closely with OCR to eliminate potential conflicts with the section 1557 final rule.

We also understand that MA organizations may need to make some administrative adjustments to comply with this requirement. CMS will provide a list of the top 15 languages most commonly spoken by individuals with LEP in each State and nationally, and OCR will provide translations of the model Notice of Availability in those languages. In addition, in this final rule we have updated §§ 422.2267(e)(31) and 423.2267(e)(33) to allow plans to continue using the MLI until the beginning of contract year 2026 marketing on September 30, 2025. However, plans will also have the choice, starting at the beginning of marketing for contract year 2025 on September 30, 2024, of using the Notice of Availability described in subparagraphs 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the MLI requirement, as provided in §§ 422.2267(e)(31)(i)(G) and 423.2267(e)(33)(i)(G). This flexibility will allow D–SNPs in States requiring a State-specific tagline to use the State tagline for contract year 2025 marketing and communications without also having to include the MLI as well. It will also allow those plans that want to provide a State-specific notice for contract year 2025 marketing and communications to do so. Per §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii), all plans will be required to use the Notice of Availability for CY 2026 marketing and communications beginning September 30, 2025.

Comment: A commenter requested that all levels of government adopt policies ensuring that individuals with LEP have adequate language access to their health care provider. The commenter also recommended we work to ensure that professional language service providers are adequately trained, certified, and compensated, and that opportunities are made available for Medicare beneficiaries, family caregivers, and trained interpreters to provide input on the language used in the model communication materials.

Response: We appreciate the commenter's perspective that professional language service providers should be adequately trained, certified, and compensated. We agree that these are important issues, although matters of compensation are beyond the scope of this rulemaking. We note that OCR will provide model language based on beneficiary testing. In addition, we encourage MA organizations to consult with Medicare beneficiaries, family caregivers, and trained interpreters if they decide to include translations of the Notice of Availability in languages other than those provided by OCR.

Comment: A few commenters recommended that we provide all standard model materials in the top 15 languages that are on the current MLI.

Response: We appreciate the commenters' recommendation, but the requests for CMS to provide translations of all standard model materials are out of scope. Our proposal pertains to notifying enrollees of the availability of verbal translation services, not the translations of written model materials themselves. However, we note that in contract year 2024, CMS did translate the Annual Notice of Changes (ANOC), Evidence of Coverage (EOC), EOC errata, Explanation of Benefits (EOB), Provider Directory, Pharmacy Directory, Formulary, Low-Income Subsidy (LIS) Rider, and Part D transition letter in Chinese, Korean, Spanish, and Vietnamese. We also remind commenters that OCR will provide translations of the model Notice of Availability in the 15 languages most commonly spoken by individuals with LEP in each State and nationally. Additionally, we note that §§ 422.2267(a)(3) and 423.2267(a)(3) obligate plans to provide required materials to enrollees on a standing basis in any of the non-English languages identified in §§ 422.2267(a)(2) or (a)(4) and 423.2267(a)(2) or (a)(4) or in an accessible format, when an enrollee makes a request to receive these materials in a non-English language or accessible format.

Comment: A few commenters stated that the 5 percent service area threshold is not inclusive enough and recommended that we set a threshold of either 5 percent or 1,000 people, whichever is lower, in a service area. Another commenter requested that there be an undefined standard to ensure that smaller language communities receive the Notice of Availability in their preferred language.

Response: We appreciate the commenters' perspectives on this issue, but changes to the threshold for the translation requirement are beyond the scope of this regulation. We believe policy making on this issue would benefit from further study and engagement with interested parties, including notice to the public and the opportunity to submit comments on this topic.

Comment: A commenter strongly encouraged us to minimize future modifications to the Notice of Availability as such fluctuations over the years have created administrative burden and increased costs for plans.

Response: We agree with the commenter that limiting future modifications to regulations regarding notification of the availability of language assistance services and auxiliary aids and services would help reduce burden. We will work to limit future changes. Moreover, we anticipate the policy we are finalizing, which better aligns Medicare translation requirements with Medicaid and OCR requirements, will mitigate the need for future updates.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to paragraphs at §§ 422.2267(e)(31) and 423.2267(e)(33) as follows: We are allowing plans a choice in the applicability date for the updates to §§ 422.2267(e)(31) and 423.2267(e)(33). Plans may implement the changes for contract year 2026 marketing and communications beginning September

30, 2025, or contract year 2025 marketing and communications beginning September 30, 2024. As a result, we are adding the heading *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability)* at §§ 422.2267(e)(31) and 423.2267(e)(33) and modifying sections §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) to read, ''Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, 'We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.'' We are then inserting the former rule sections §§ 422.2267(e)(31)(i)–(vi) and 423.2267(e)(33)(i)–(vi) and renumbering them as §§ 422.2267(e)(31)(i)(A)–(F) and 423.2267(e)(33)(i)(A)–(F). We are also including a clarification in §§ 422.2267(e)(31)(i)(B) and 423.2267(e)(33)(i)(B) to incorporate the exception that we are finalizing in §§ 422.2267(e)(31)(i)(G) and 423.2267(e)(33)(i)(G), which will allow plans to utilize the new model notice described in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the existing MLI requirement during contract year 2025. We are also adding § 422.2267(e)(31)(i)(G) stating, ''At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in subparagraph 422.2267(e)(31)(ii) to satisfy the MLI requirements set forth in this subparagraph (i).'' We are adding an identical provision at § 423.2267(e)(33)(i)(G) except with a reference to subparagraph 423.2267(e)(33)(ii).

We are modifying sections §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to state, ''For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.'' We are then redesignating sections §§ 422.2267(e)(31)(i)–(vi) and 423.2267(e)(33)(i)–(vi) as new paragraphs §§ 422.2267(e)(31)(ii)(A)–(G) and 423.2267(e)(33)(ii)(A)–(G). For the redesignated paragraphs (e)(31)(ii)(A) and (e)(33)(ii)(A) we are adding ''or States associated with the plan's service area'' between the proposed language ''relevant State'' and ''and must be provided . . .'' to reduce the burden on organizations with plan benefit packages that operate in more than one State and conform with the section 1557 proposed rule, and to clarify that the requirement is based on the plan benefit package service area. Paragraph (A) will specify that this notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

Q. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

Section 1853(a) of the Act requires CMS to risk-adjust payments made to Medicare Advantage (MA) organizations. In order to carry out risk adjustment, section 1853(a)(3)(B) of the Act requires submission of data by MA organizations regarding the services provided to enrollees and other information the Secretary deems necessary. The implementing regulation at § 422.310(b) requires that MA organizations submit to CMS ''the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner.'' Currently, § 422.310(d)(1) provides that MA organizations submit risk adjustment data equivalent to Medicare fee-for-service (FFS) data to CMS as specified by CMS. MA encounter data, which are comprehensive data equivalent to Medicare FFS data, are risk adjustment data.[73]

Section 1106(a)(1) of the Act authorizes the Secretary to adopt regulations governing release of information gathered in the course of administering programs under the Act. In addition, section 1856(b) of the Act authorizes CMS to adopt standards to carry out the MA statute, and section 1857(e)(1) of the Act authorizes CMS to add contract terms that are not inconsistent with the Part C statute and are necessary and appropriate for the program. The regulation at § 422.310(f)(1) establishes permissible CMS uses of MA encounter data (referred to as ''risk adjustment data'' in the regulation), while § 422.310(f)(2) and (f)(3) establish rules for CMS release of data. Prior to 2008, § 422.310(f) provided for CMS to use MA risk adjustment data to risk adjust MA payments and, except for any medical record data also collected under § 422.310, for other purposes. Over time, we subsequently refined the regulatory language describing the scope of permissible uses and releases of the MA risk adjustment data, including MA encounter data, to (i) risk adjusting MA payments, (ii) updating risk adjustment models, (iii) calculating Medicare disproportionate share hospital percentages, (iv) conducting quality review and improvement activities, (v) for Medicare coverage purposes, (vi) conducting evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related purposes, (vii) for activities to support administration of the Medicare program, (viii) for activities to support program integrity, and (ix) for purposes authorized by other applicable laws (70 FR 4588; 73 FR 48650 through 48654; 79 FR 50325 through 50334).

Section 422.310(f)(2) permits the release of MA encounter data to other HHS agencies, other Federal executive branch agencies, States, and external entities, and § 422.310(f)(3) of our current regulation specifies circumstances under which we may release MA encounter data for the purposes described in § 422.310(f)(1). Existing regulations allow release of the data after risk adjustment reconciliation for the applicable payment year has been completed, under certain emergency preparedness or extraordinary circumstances, and when CMS determines that releasing aggregated data before reconciliation is necessary and appropriate for activities to support the administration of the

[73] See System of Records Notices for the CMS Encounter Data System (EDS), System No. 09–70–0506, published June 17, 2014 (79 FR 34539), as amended at February 14, 2018 (83 FR 6591); and for the CMS Risk Adjustment Suite of Systems (RASS), System No. 09–70–0508, published August 17, 2015 (80 FR 49237), as amended at February 14, 2018 (83 FR 6591).

Medicare program (finalized in the CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program final rule (88 FR 79400)). We noted in the November 2023 proposed rule that further expanding MA encounter data sharing to include support for the Medicaid program would be consistent with the goals of the Federal Coordinated Health Care Office, as established in statute (88 FR 78527).

MA enrollment has grown to approximately half of all Medicare beneficiaries; a trend also seen in the enrollment of dually eligible individuals. For example, 51 percent of all dually eligible individuals were enrolled in an MA plan in 2021 (up from 12 percent in December 2006).[74] [75] Such individuals experience the health care system and incur health outcomes as individuals regardless of which health care program pays for the service, but currently, the States' ability to obtain MA encounter data for program analysis and evaluations or program administration for dually eligible individuals enrolled in an MA plan is limited to support of a Medicare-Medicaid demonstration. Our current regulation text does not specify that we may make MA encounter data available to States for Medicaid program administration or to conduct evaluations and other analyses for the Medicaid program, with the exception of those evaluations and analyses used to support demonstrations. Therefore, previous rulemaking limited opportunities for States to effectively perform functions such as coordination of care, quality measure design, and program evaluation and analysis by allowing them access to MA encounter data for these activities only for those dually eligible individuals enrolled in Medicare-Medicaid demonstrations.

We proposed changes to § 422.310(f) to improve States' access to MA encounter data, including making a specific exception to the timing of sharing MA encounter data. We noted that we did not intend for our proposals to impact the terms and conditions governing CMS release of MA risk adjustment data as described in § 422.310(f)(2), in accordance with applicable Federal laws and CMS data sharing procedures. As discussed in the August 2014 final rule, CMS data sharing procedures require each recipient of data from CMS to sign and maintain a CMS data sharing agreement, ''which addresses privacy and security for the data CMS discloses'' and ''contains provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is stored in a secure system and handled according to CMS's security policies,'' which encompasses the limitations for additional disclosure of CMS data (79 FR 50333). We noted that such provisions would similarly apply to States that receive MA encounter data under our proposed amendments to § 422.310(f).

As stated in the August 2014 final rule, the data described in paragraphs (a) through (d) would include those elements that constitute an encounter data record, including contract, plan, and provider identifiers, with the exception of disaggregated payment data (79 FR 50325). In accordance with § 422.310(f)(2)(iv), we aggregate payment data to protect commercially sensitive information.

1. Expanding and Clarifying the Programs for Which MA Encounter Data May Be Used for Certain Allowable Purposes

As we stated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program proposed rule (hereafter referred to as the May 2014 proposed rule; 79 FR 27978), using MA encounter data enables us, our contractors, and external entities to support Medicare program evaluations, demonstration designs, and effective and efficient operational management of the Medicare program, encourages research into better ways to provide health care, and increases transparency in the administration of the Medicare program (79 FR 28281 through 28282). However, because States lack access to MA encounter data, States' ability to conduct activities for dually eligible individuals enrolled in MA plans is limited. As Medicare is the primary payer for dually eligible individuals, States generally lack comprehensive data on care provided to dually eligible individuals enrolled in MA. Over the years, various States have requested that CMS share MA encounter data for dually eligible individuals to better coordinate care, conduct quality improvement activities, support program design, conduct evaluations, and improve efficiency in the administration of the Medicaid program.

Our current regulation text at § 422.310(f)(1)(vi) (evaluations and analysis to support the Medicare program) and (vii) (activities to support administration of the program) specifies that, for these purposes, the encounter data must be used for the Medicare program. Therefore, though § 422.310(f)(2) permits CMS to release MA encounter data to States for the purposes listed in paragraph (f)(1), § 422.310(f)(1)(vi) and (vii) do not clearly permit CMS to release MA encounter data to States to support Medicaid program evaluations and analysis or to support administration of the Medicaid program.

We proposed to add ''and Medicaid program'' to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii) and explained that these additions would enable CMS to use the data and release it (in accordance with § 422.310(f)(2) and (3)) for the purposes of evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes. We stated our belief that our release of MA encounter data for data use purposes that support the Medicare and Medicaid programs would generally be to the States and would support our responsibility to improve the quality of health care and long-term services for dually eligible individuals; improve care continuity, ensuring safe and effective care transitions for dually eligible individuals; improve the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs for dually eligible individuals; and support State efforts to coordinate and align acute care and long-term care services for dually eligible individuals with other items and services furnished under the Medicare program.

We noted in the November 2023 proposed rule that, as stated above, CMS's usual data sharing procedures apply to the release of MA encounter data in accordance with § 422.310(f)(2) and address access to and storage of CMS data to ensure that beneficiary identifiable information is protected. We explained that we make other data available to external entities, including

[74] 2023 Medicare Trustees Report *https://www.cms.gov/oact/tr.*

[75] *https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief2012-2021.pdf.*

States, in accordance with CMS data sharing procedures and Federal laws, including but not limited to the Privacy Act of 1974. We further explained that we review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests, and we employ data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure of CMS data. For example, States that request data from CMS for care coordination and program integrity initiatives may disclose the data to State contractors, vendors, or other business associates for those activities. In accordance with CMS data sharing agreements, these State contractors, vendors, or other business associates must also follow the terms and conditions for use of the CMS data, including limiting use of the CMS-provided data only for approved purposes. We explained that this would mean that, under our proposal, a State receiving MA encounter data for care coordination may disclose MA encounter data to Medicaid managed care plans to coordinate services for enrolled dually eligible individuals. We noted that comments submitted on the August 2014 final rule cited concerns that access to MA encounter data by competitors of the various MA organizations that are required to submit data could permit a competitor to gain an advantage by trending cost and utilization patterns over a number of years. We explained that § 422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to States would comply with applicable statutes, regulations, and processes including those described above, and we expressed our belief that concern around potential competitive advantage would be mitigated if the risk exists at all. We noted that, as stated in the August 2014 final rule, we believe that CMS data sharing procedures and review of use justifications ''strikes an appropriate balance between the significant benefits of furthering knowledge'' and the concerns regarding the release of risk adjustment data, including about beneficiary privacy or commercially sensitive nature of encounter information submitted by MA plans (79 FR 50328). Consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requestors acknowledge these mechanisms. For example, penalties under section 1106(a) of the Social Security Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties that may be imposed under 18 U.S.C. 641 (79 FR 50333). Requestors of CMS data, such as States, are responsible for abiding by the law, policies, and restrictions of the data sharing agreements—which extends to any downstream disclosures of the data to State contractors, vendors, or other business associates—as a condition of receiving the data. We noted our intent to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to State contractors, vendors, or other business associates—for each requested purpose. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs.

As stated in the November 2023 proposed rule, this proposal would allow us to use MA encounter data and disclose it—subject to the other limitations and protections specified in § 422.310(f) and other applicable laws and regulations—to States to perform evaluations and analysis, which would include program planning for dually eligible individuals. Currently, States generally only receive Medicare FFS data from CMS under current authorities, which results in an incomplete assessment of the dually eligible population. Under our proposal, we noted that States could request MA encounter data for all of the dually eligible enrollees they serve and include this growing portion of the dually eligible population in their data analysis and efforts to improve outcomes for low-income older adults and people with disabilities who are enrolled in the Medicaid program.

In the August 2014 final rule, we stated that, in addition to use of these data for review of bid validity and MLR, we expected there would be additional potential uses for these data as part of the program administration purpose, such as the development of quality measures (79 FR 50326). Consistent with our expectation at that time, we clarified in the November 2023 proposed rule that care coordination would be an allowable use for these data as part of the purpose currently codified at § 422.310(f)(1)(vii)—for activities to support the administration of the Medicare program—which includes activities that are not within the scope of the other permitted uses defined at § 422.310(f)(1). Similar to quality measure development, a use we explicitly named, care coordination is critical to ensuring that individuals receive effective and efficient care, especially when services may be covered under multiple health care programs, as is the case for dually eligible individuals who are enrolled in Medicaid and an MA plan. We also stated our belief that use and release of MA encounter data to States to support administering the Medicaid program, including to coordinate care and improve quality of care for Medicaid-covered individuals, is appropriate. We provided the example that, in administering the Medicaid program, a State may need MA encounter data to coordinate care for dually eligible individuals, which may include identification of individuals at high risk of institutional placement or other undesirable outcomes based on past service utilization; coordination of services from the MA plan's coverage of an inpatient stay to Medicaid coverage of subsequent home and community-based services; coordination of Medicaid-covered services in a skilled nursing facility for a dually eligible individual after reaching the limits of the individual's coverage through the MA plan; monitoring nursing facility quality of care, including through tracking rates of hospitalization and emergency room visits; and coordination of physical health services with behavioral health services, where Medicaid coverage differs from the MA plan's coverage.

2. Adding an Additional Condition Under Which MA Encounter Data May Be Released Prior to Reconciliation

Section 422.310(f)(3) describes the circumstances under which we may release MA encounter data. Specifically, the current regulation provides that MA encounter data will not become available for release unless the risk adjustment reconciliation for the applicable payment year has been completed, we determine it is necessary for certain emergency preparedness purposes, we determine that extraordinary circumstances exist, or we determine that releasing aggregated data is necessary and appropriate to support activities and authorized uses in the administration of the Medicare program. Section 422.310(g) specifies the deadlines that we use to determine which risk adjustment data submissions we will use to calculate risk scores for a given payment year. This section also establishes a reconciliation process to adjust payments based on additional data from the data collection period

(meaning the year the item or service was furnished to the MA enrollee) so long as we receive the submissions before the established final risk adjustment data submission deadline for the payment year, which is no earlier than January 31 of the year following the payment year. This submission window provides MA organizations an opportunity to update or submit encounter data records and chart review records to be considered for risk adjustment and payment in the applicable payment year. Section 422.310(b) requires MA organizations to submit data for all items and services provided to an MA enrollee; therefore, MA organizations must continue to submit encounter data records and data corrections after the final risk adjustment data submission deadline when timely data submissions are determined to be inaccurate, incomplete, or untruthful (see § 422.310(g)(2)(ii) for limitations on which submissions after the final risk adjustment data submission deadline may be used for additional payment). We explained that the timing limitation on release of MA encounter data in our current regulation is tied to the established final risk adjustment data submission deadline for a given payment year, and it results in a data lag of at least 13 months after the end of the MA risk adjustment data collection period (that is, the year during which the item or service was furnished to the MA enrollee), before CMS may release the MA risk adjustment data for the purposes described in § 422.310(f)(1). In the November 2023 proposed rule, we stated our belief that there will be increased utility of MA encounter data for Medicaid programs if the data is released before final risk adjustment reconciliation for coordination of care under the allowable purpose in § 422.310(f)(1)(vii) and that the reasons and concerns we identified when adopting the delay in release of MA encounter data can be sufficiently taken into account by CMS as part of evaluating a request to use the data for specific purposes and determining whether to release the data. Further, in many cases, those reasons and concerns likely do not sufficiently apply in the context of care coordination to require a delay in releasing the data, the further discussion of which we recount below.

In order to improve utility of MA encounter data for certain approved purposes, we proposed to add a new paragraph (f)(3)(v) to § 422.310 to authorize MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before the final risk adjustment reconciliation for a relevant year is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). As discussed in the November 2023 proposed rule, the proposed amendment to § 422.310(f)(1)(vii) would expand the scope of that provision to include using the data to support administration of the Medicaid program, and in our discussion, we clarified that coordination of care activities are within the scope of activities that support administration of these health care programs. We specified care coordination in our discussion of the proposal for release of MA encounter data prior to final risk adjustment reconciliation, because, as we explained in the November 2023 proposed rule, we believe providing States access to this more timely data is critical to effectively coordinating care which is directly tied to our responsibility to support States' efforts to coordinate and align care and services for dually eligible individuals and furthers our goal to improve care continuity and ensure safe and effective care transitions for dually eligible individuals (see 42 U.S.C. 1315B) while accommodating the concerns that led us to adopt the time limits in § 422.310(f)(3). Together, the proposed changes to § 422.310(f)(1)(vii) and (f)(3)(v) would improve the timeliness of the MA encounter data we make available to States for coordination of care for dually eligible individuals. For care coordination activities, States rely more on timely data about service utilization than on complete data. We stated our belief that improving access to timely MA encounter data and ensuring Medicaid programs can coordinate care for dually eligible individuals supports our goal of providing dually eligible individuals full access to the benefits to which they are entitled (42 U.S.C. 1315B(d)).

As discussed above, States cannot effectively coordinate care for individuals using data that is more than one or two years old. We recognize that the MA encounter data may be subject to edits before final risk adjustment reconciliation given the final risk adjustment data submission deadline for submission of risk adjustment data under § 422.310(g)(2)(ii), which states that the final risk adjustment data submission deadline is a date no earlier than January 31 of the year following the payment year. Therefore, data from some MA organizations or for some enrollees may not be available as quickly as data from or for others. However, we explained that we believe that earlier release of MA encounter data to States for the purpose of care coordination for dually eligible individuals would be appropriate and, as stated above, many of the reasons and concerns to require a delay releasing MA encounter data likely do not sufficiently apply in the context of care coordination. Care coordination activities require States, or their contractors, to identify and contact individuals who have received or are in need of services from their providers. We explained that as States would use the MA encounter data to identify opportunities for care improvement such as improving transitions of care or promoting the use of underutilized services, we did not foresee any risk to individuals from States using data that may be subject to change in the future. States would be able to use the data to identify more dually eligible individuals who are potentially in need of Medicaid-covered services. States are not required to act on the data and can address potential data concerns arising from using MA encounter data before final risk adjustment reconciliation as States have experience using Medicare data that may not be final for effective care coordination. We noted that many States already obtain timely Medicare FFS claims with a lag between 14 days to 3 months, depending on the data file, for uses such as care coordination, quality improvement, and program integrity. These Medicare FFS claims may also be subject to change subsequent to the States' receipt of the data, yet we are not aware of any problems in these use cases caused by CMS sharing data that is still subject to change. Because the MA encounter data released to States would be for care coordination purposes, we do not anticipate any negative impacts from any potential subsequent changes to the encounters. MA encounter data made available to States prior to final risk adjustment reconciliation would not contain disaggregated payment information, in accordance with § 422.310(f)(2)(iv). Additionally, States will not use the pre-reconciliation MA encounter data for plan payment. Under our proposal, release of the MA encounter data for care coordination purposes must be necessary and appropriate to support administration of the Medicaid program; we stated our belief that it would not be appropriate or necessary to use the MA data released on this accelerated schedule for payment purposes (88 FR 78530).

As we explained in the November 2023 proposed rule, coordination of care is a clear situation where more timely MA encounter data is needed for effective intervention without invoking risks that we have cited in the past about sharing MA risk adjustment data before final risk adjustment reconciliation. The timing limits in § 422.310(f)(3) were adopted in the August 2014 final rule in response to comments expressing concern about release of the MA risk adjustment data (79 FR 50331 through 50332). In that prior rulemaking, some commenters cited concerns about release of MA encounter data submitted in the initial years due to concerns regarding systems development and submission challenges. We stated our belief that these concerns were mitigated by the subsequent years since the implementation of the August 2014 final rule that have resulted in accumulation of experience submitting, reviewing, and using MA encounter data in accordance with § 422.310(f). We noted that, in addition, CMS maintains several checks and edits in the encounter data system to minimize duplicate, incomplete, or inappropriate data stored in the encounter data system. In the November 2023 proposed rule, we reiterated that our proposed amendment to paragraph (f)(3) would only permit the release of MA encounter data to State Medicaid agencies for care coordination for dually eligible individuals.

We also explained that we had noted in prior rulemaking that our approach to reviewing requests for MA encounter data from external entities would incorporate the Medicare Part A/B and Part D minimum necessary data policy, with additional restrictions to protect beneficiary privacy and commercially sensitive information of MA organizations and incorporated that limitation into paragraph (f)(2) (79 FR 50327). Further, we noted that this limitation would also apply when reviewing State requests for MA encounter data under the proposed expansion of § 422.310(f)(1)(vi) and (vii), and to any State requests for MA encounter data before the reconciliation deadline to support coordination of care. We explained that CMS data sharing procedures include a review team that assesses data requests for minimum data necessary and appropriate use justifications for care coordination, and we would only approve release of MA encounter data for any data requests where the requestor has sufficiently demonstrated that the request satisfies all requirements of § 422.310(f). We noted that other commenters on the August 2014 final rule had expressed concerns that MA organizations are able to delete, replace, or correct MA encounter data before the reconciliation deadline, which could potentially result in inaccurate or incomplete MA encounter data and that incomplete or inaccurate data should not be used or released for the purposes outlined in § 422.310(f). Additionally, CMS makes available technical assistance to States to help with State use and understanding of Medicare data. In the November 2023 proposed rule, we expressed our intent to extend this technical assistance to States requesting MA encounter data to mitigate issues arising from non-final data, and to evaluate the potential concerns arising from using MA encounter data before final reconciliation when determining whether to release MA encounter data to States for care coordination activities for dually eligible individuals to support administration of the Medicare and Medicaid programs.

Finally, we proposed that these amendments to § 422.310(f) would be applicable upon the effective date of the final rule. As outlined in section I.A. of the November 2023 proposed rule, the majority of our proposals were proposed to be applicable beginning January 1, 2025. We stated that we do not believe delaying the applicability of these proposed amendments beyond the effective date of the final rule is necessary because these proposals address CMS's authority to use and share MA encounter data but do not impose any additional or new obligations on MA organizations.

We received the following comments on these two proposals and respond to them below:

Comment: Numerous commenters, including the vast majority who commented on these proposals, expressed support for CMS proposals to expand the allowable MA encounter data uses by adding ''and Medicaid'' to existing uses at § 422.310(f)(1)(vi) and (vii) and our proposal to share MA encounter data with States in advance of reconciliation for the purpose of care coordination for dually eligible individuals. These commenters agreed that these changes would improve States' ability to understand and improve service delivery for dually eligible individuals. Many comments also included additional perceived benefits, such as: identification of unaligned dually eligible individuals (that is, individuals enrolled in one MA plan and a separate, unaligned Medicaid managed care plan); D–SNP program planning; assessing supplemental benefit use; facilitating development of a long term services and supports dashboard to inform policy and quality improvement efforts; ensuring proper payment for services and determination of third party liability with minimal disruption to providers; focusing outreach for service provision by Medicaid managed care plans; analysis for required reporting on managed care network adequacy and service access; eliminating potentially duplicative evaluations; and providing continuity within both primary and specialty care for dually eligible individuals.

Response: We appreciate the comments and support.

Comment: A commenter requested clarification on how the facilitation of the data exchange may occur and if this requires data exchange agreements, three-way contracts, business associate agreements, or other contractual arrangements.

Response: To effectuate encounter data sharing with States, we would utilize our existing pathways for new data requests, including the existing data transfer mechanisms and data sharing agreements that we currently hold with the States for the disclosure of Medicare data. As stated in the proposed rule, we ''review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests'' and ''employ data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure of CMS data'' (88 FR 78528).

Comment: Many commenters supported CMS's intent to provide technical assistance and emphasized its importance. A few of those commenters provided suggestions on technical assistance that we could provide to States for encounter data, including sharing information on best practices for utilizing the data; content and limitations of the data set; data request processes and timelines; disclosure parameters and suggested uses for the data; purposes not permitted; data linkage; and building data infrastructure for use of MA encounter data.

Response: We thank these commenters for their suggestions. We agree that technical assistance to States would be an important aspect of sharing MA encounter data. As we noted in our proposal, we intend to provide technical assistance to States, such as the CCW Medicare Encounter Data User Guide (*https://www2.ccwdata.org/web/guest/user-documentation*), to help them make the most effective use of MA

encounter data, including ways to mitigate issues arising from non-final data, potential concerns arising from using MA encounter data before final reconciliation, and what disclaimers are appropriate to provide to requestors, to help them understand the limitations of the MA encounter data (88 FR 78531). We will take these suggestions into consideration when developing our technical assistance approach.

Comment: A commenter provided additional suggestions for our communication around sharing of MA encounter data with States. These suggestions included notifying plans when MA encounter data is shared with a State, guidance to States on how to communicate with plans and address anomalies, particularly when the State is analyzing and interpreting these data for performance evaluation and quality reporting, and publishing a report following 2 years of implementation that provides the industry with information on how the sharing of MA encounter data has facilitated greater coordination, integration, and quality measure alignment.

Response: We thank the commenter for these suggestions. We will take them into consideration as we establish operational processes to support sharing MA encounter data with States.

Comment: A commenter supported CMS proposals and suggested CMS include other data collected from or submitted by MA organizations, such as data obtained from chart reviews, lab results, EMR records, and other clinical documents, in addition to MA encounter data in the data that is shared with States under § 422.310(f).

Response: We note that current regulation at § 422.310(f) specifies the purposes and procedures according to which we may use and release the MA risk adjustment data, which is defined in § 422.310(a) and includes encounter data and other data submitted by MA organizations for risk adjustment purposes (such as chart review records, which are reports of diagnoses, and may be sourced from chart reviews, lab results, EMR record or other clinical documents). However, aside from the chart review records, any clinical documentation that CMS may have access to will not be released. The regulation at § 422.310(f) excludes the use and release of the data described at § 422.310(e) for validation of risk adjustment data; this means that the medical records or other clinical documents that MA organizations submit to validate their risk adjustment submissions are not released under § 422.310(f). CMS did not propose any changes to expand data sharing to include medical records or other clinical documents; therefore, CMS is not finalizing any regulatory changes related to sharing such information.

Comment: Some commenters stressed the importance of establishing strong measures to ensure data privacy and security when disclosing MA encounter data, including limiting access to medical records to protect the trust and security of the physician-patient relationship and the safety of the patient.

Response: We appreciate these comments underscoring the importance of protecting data privacy and security. In the proposed rule, we stated that we disclose data in accordance with applicable Federal laws and CMS data sharing procedures that include privacy and security measures for data sharing to protect individuals' PHI and PII, (88 FR 78527). We also noted in our proposed rule the following additional CMS data sharing processes to protect the safety of the individual: we review data requests for appropriate use justifications, employ data sharing agreements that limit data requestors to CMS-approved data uses and disclosure of CMS data, and include enforcement mechanisms; and data requestors acknowledge these mechanisms and that they will abide by the law, policies, and restrictions of the data sharing agreements as a condition of receiving the data (88 FR 78528). We will only approve data requests that are within the allowable uses of MA risk adjustment data (generally MA encounter data) as detailed in § 422.310(f)(1). With regard to the comment about limiting access to medical records, as discussed in a prior response to a public comment, § 422.310(f) does not authorize the release of medical records or other records submitted by an MA organization under § 422.310(e) to validate its risk adjustment data submissions.

Comment: Some commenters underscored the importance of data quality and provided recommendations to ensure data accuracy and completeness. These recommendations included suggesting that CMS continue to seek ways to improve the completeness of encounter data, including considering MedPAC's 2019 recommendation on MA encounter data completeness; considering ways to ensure that data is as accurate as possible when shared to avoid incorrect care planning and potential patient harm; and providing further clarity on how this data will be communicated. Additionally, a commenter recommended CMS avoid any changes that may impact data quality or how MA organizations currently report to CMS and State Medicaid programs.

Response: We thank these commenters for the recommendations to ensure data quality and accuracy. We reiterate our intent to provide technical assistance and necessary resources for data requestors, including appropriate disclaimers to help requestors understand the limitations of the MA encounter data (88 FR 78531). We stated in the proposed rule that we do not foresee any potential patient harm from States using data that may be subject to change in the future since States would use the MA encounter data to identify opportunities for care improvement, such as improving transitions of care or to promote the use of underutilized services, and that States are not required to act on the data. We also explained that States have experience using Medicare data that may not be final for effective care coordination (88 FR 78530). We appreciate MedPAC's 2019 recommendations and note that we have been working with MA plans to ensure that the accuracy and completeness of MA encounter data improve over time. We note that we have released the *Request for Information: Medicare Advantage Data* to solicit feedback ''on all aspects of data related to the MA program—both data not currently collected as well as data currently collected,'' including ''precise detail and definitions on the data format, fields, and content that would facilitate comprehensive analyses of any publicly released MA data, including comparisons with existing data sets'' and ''recommendations related to operational considerations as part of this effort'' (89 FR 5907 through 5908).

Additionally, we confirm that our proposal does not impact how MA plans submit MA encounter data to CMS. As mentioned above, we will utilize our existing pathways for new MA encounter data requests, including the existing data transfer mechanisms.

Comment: A commenter raised the concern that in order for the proposed policies to be meaningful, States would need necessary resources and infrastructure in place to utilize MA encounter data effectively. The commenter also explained that it is important to coordinate with States to understand their current and planned capacity for ingesting and utilizing the MA encounter data before proceeding. The commenter further stressed that without sufficient IT supports and specific plans for how to leverage MA encounter data, providing the data as proposed would not achieve CMS's goals. Another commenter suggested

that MA encounter data be available at the discretion of the State, as with other Medicare data sharing, as not all State systems are sophisticated enough to use this data.

Response: We appreciate the comments regarding States' capabilities for intake and analysis of the MA encounter data. Many States have extensive history with encounter data through their Medicaid managed care programs. Many also have experience working with Medicare FFS and MA encounter data. For example, since 2011, we have disclosed Medicare data to States to support the dually eligible population, and over 30 States have requested and used, or are still using, these data. Another example is that numerous States currently receive and use MA encounters directly from MA plans in accordance with the terms of a demonstration or as detailed by the contract held by a D–SNP with the State. Additionally, our data sharing agreements require States attest to certain requirements regarding appropriate administrative technical and physical safeguards to protect the integrity, security, and confidentiality of the data as well as system security requirements in order to request data from us. Nonetheless, capacity and experience vary across States, and we confirm our stated intention in the proposed rule that MA risk adjustment data would be available, consistent with § 422.310(f) as amended, when the State requests such data; a State's request for MA encounter data from CMS would be voluntary.

Comment: A few commenters raised questions regarding duplicative data sharing practices and the requirements in some State Medicaid agency contracts (SMACs) for D–SNPs to submit MA encounter data directly to States. A commenter asked how the proposed change would impact existing SMAC requirements, which may currently require such data sharing between D–SNPs and the State, and whether our proposal would create redundancies, inefficiencies, or simply obviate the need for such data sharing. A commenter wished to avoid duplicating any data sharing practices currently in place, and suggested we collaborate with MA plans and States to determine if data sharing can be streamlined through one process. Another commenter suggested removing the requirement for D–SNPs to submit MA encounter data directly to States and, instead, CMS would create a uniform set of MA encounter data available from a central organization, eliminating 50 different systems that collect data in different ways, formats, and times.

Response: We appreciate the interest in streamlining data sharing processes and will consider these comments as we implement the final rule. However, nothing in our final rule imposes any additional or new obligations on MA organizations (88 FR 78531) or creates any additional data sharing or data reporting burden for MA plans. These comments relate to MA encounter data that D–SNPs submit to States in accordance with SMACs established under § 422.107(d)(1). Changes to SMAC requirements about data sharing or data access are outside the scope of our current proposals and are subject to negotiation between the MA organization (or D–SNP) and the State; our current proposals do not directly impact these SMAC requirements or data sharing processes.

Comment: A commenter suggested that CMS provide additional resources for MA organizations on collecting encounter data, citing burdens associated with collecting, processing, and submitting the data. Another commenter suggested that CMS encourage MA plans to submit more timely, higher quality, and uniform MA encounter data directly to States to improve usability for time-sensitive care coordination.

Response: We believe that these suggestions for additional resources for MA organizations to collect MA encounter data and encouraging MA plans to submit more timely, higher quality data directly to States are beyond the scope of this rule. However, as mentioned above, we released the *Request for Information: Medicare Advantage Data* to solicit additional feedback on all aspects of data related to the MA program, including ways that we could improve our current MA data collection and release methods (89 FR 5907).

Comment: A commenter recommended CMS create data sharing agreements to exclude downstream disclosure of MA encounter data to commercial entities. Another commenter expressed concern that changes made by Congress or CMS could expand the type of information captured by MA encounter data in the future to include competitively sensitive information that should not be shared with States. This commenter said that CMS should create an explicit exclusion of payment and pricing data and other competitively sensitive information, indicating that only MA encounter data necessary to support coordination of care, quality measure design, and program evaluation and analysis be shared with States.

Response: As stated in the proposed rule, we intend to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to State contractors, vendors, or other business associates—for each requested purpose (88 FR 78528). Also, consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requestors acknowledge these mechanisms. For example, penalties under section 1106(a) of the Social Security Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties may be imposed under 18 U.S.C. 641 (79 FR 50333). Requestors of CMS data, such as States, are responsible for abiding by the law, policies, and restrictions of the data sharing agreements—which extends to any downstream disclosures of the data to State contractors, vendors, or other business associates—as condition of receiving the data. Additionally, we note that current regulation at § 422.310(2)(iv) limits CMS release of MA encounter data ''(s)ubject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.'' We stated in the proposed rule that—given that § 422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to States would comply with applicable statutes, regulations, and processes including those described above—we believe that concern around potential competitive advantage is mitigated, if the risk exists at all. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs, including current disclosure of MA encounter data (88 FR 78528).

Finally, we note that in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the

Medicare Promoting Interoperability Program final rule (hereinafter referred to as the January 2024 final rule), we finalized a requirement for impacted payers to employ a Payer-to-Payer API by January 1, 2027 to satisfy two requirements: first, for transfer of data from a previous payer to a current payer for a new enrollee, and second, for quarterly exchange of data between two concurrent payers. Impacted payers include States, Medicaid managed care plans, and MA plans, and therefore would apply to individuals dually enrolled in two or more of these payers—such as between an MA organization and a Medicaid managed care plan (89 FR 8759).

Comment: We received a comment on our discussion in section XI of the November 2023 proposed rule (88 FR 78605), which provided examples where the commenter felt we inadequately justified the need for rulemaking. Specific to our MA encounter data use proposals in this section, the commenter suggested that we include the number of States that have requested such data and provide more specific information about how the wording of the current rule has harmed coordination and quality of care.

Response: As described in the proposed rule, 51 percent of all dually eligible individuals were enrolled in an MA plan in 2021, but previous rulemaking limited opportunities for States to effectively perform functions such as coordination of care, quality measure design, and program evaluation and analysis by allowing them access to MA encounter data for these activities only for those dually eligible individuals enrolled in Medicare-Medicaid demonstrations (88 FR 78527). We also noted in the proposed rule that ''(a)s Medicare is the primary payer for dually eligible individuals, States generally lack comprehensive data on care provided to dually eligible individuals enrolled in MA'' and that ''(o)ver the years, various States have requested that CMS share MA encounter data for dually eligible individuals to better coordinate care, conduct quality improvement activities, support program design, conduct evaluations, and improve efficiency in the administration of the Medicaid program'' (88 FR 78527). We further clarify here that while we do not have a definitive list of all the States that would have requested MA encounter data if it were made available, our contractor conducted an informal poll in 2017 of the States that requested Medicare FFS data and found that 14 out of 15 respondents were interested in requesting MA encounter data if made available. Additionally, during 2022, four States directly asked us for MA encounter data to support specific projects related to dually eligible individuals. In 2023, 26 States (and the District of Columbia) requested Medicare data for dually eligible individuals for care coordination, quality improvement, program planning, and program integrity data uses. The remaining 25 States that did *not* request Medicare data for such uses had various levels of engagement and interaction with our program. Over the previous decade, some of those 25 non-participating States with high managed care penetration cited the lack of MA encounter data as the reason the State did not request Medicare FFS data via our data sharing program.

In the proposed rule, we provided numerous examples of ways States could use MA encounter data. These examples included identification of individuals at high risk of institutional placement or other undesirable outcomes based on past service utilization; coordination of services from the MA plan's coverage of an inpatient stay to Medicaid coverage of subsequent home and community-based services; coordination of Medicaid-covered services in a skilled nursing facility for a dually eligible individual after reaching the limits of the individual's coverage through the MA plan; monitoring nursing facility quality of care, including through tracking rates of hospitalization and emergency room visits; and coordination of physical health services with behavioral health services, where Medicaid coverage differs from the MA plan's coverage (88 FR 78528). As the current regulation at § 422.310(f) does not permit CMS to disclose MA encounter data to States for these data uses, we believe there is harm incurred when States are unable to conduct these activities for dually eligible individuals. We note that we do not know the full extent of States that would have requested MA encounter data if current regulation permitted, the exact data uses for which the States would have used the data, or the number of dually eligible individuals impacted by such data-driven initiatives. However, based on our experience and observations, we believe that it is appropriate to conclude that access to MA risk adjustment data on an accelerated timeframe could support State efforts to coordinate care for dually eligible individuals who are in MA plans.

Finally, as stated in the proposed rule, we believe disclosure for the purpose of improving States' ability to understand and improve care provided to dually eligible individuals is appropriate and consistent with our intention in prior rulemaking regarding uses of MA risk adjustment data and proposed changes to regulation to support our intention (88 FR 78526).

Comment: A commenter recommended additional data sharing efforts for CMS to undertake to improve care coordination for dually eligible individuals. The commenter suggested CMS establish a database with Medicare data for all dually eligible individuals—including Medicare program and contract enrollment data, as well as their Medicare claims data—and disclose to States and plans for coordination across payers. The commenter also suggested requiring States to share standard elements (for example, Medicare program enrollment, Medicare contract number) to Medicaid managed care plans in standard benefit enrollment and maintenance files to facilitate coordination for dually eligible individuals.

Response: We appreciate the suggestions, but they are outside of the scope of our proposal.

After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment to add ''and Medicaid program'' to the current MA encounter data use purposes at § 422.310(f)(1)(vi) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research, and § 422.310(f)(1)(vii) for activities to support the administration of the Medicare program. We are also finalizing without modification our proposed addition of new § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). These amendments to § 422.310(f) will be applicable upon the effective date of this final rule as outlined in section I.A. of this final rule. As explained in the proposed rule, delaying the applicability of these proposed amendments beyond the effective date of the final rule is not necessary because these proposals address CMS's authority to use and share MA risk adjustment data but do

not impose any additional or new obligations on MA organizations.

3. Solicitation of Comments on Use of MA Encounter Data To Support Required Medicaid Quality Reporting

We requested comments on making MA encounter data available to States to support Child and Adult Core Set reporting as efficiently as possible while complying with § 422.310(f) and balancing considerations related to the timeliness of quality reporting with accuracy and completeness. While States are required to include all Medicaid and CHIP beneficiaries in certain mandatory Child and Adult Core Set reporting, including dually eligible individuals, States lack access to the Medicare utilization data needed to report on dually eligible individuals enrolled in MA plans. We discussed these mandatory Core Set reporting requirements and the timing limitations posed by our current regulations in the November 2023 proposed rule (88 FR 78531).

Several commenters supported CMS sharing MA encounter data to States prior to reconciliation for quality review and improvement use. A commenter suggesting alternative options to using MA encounter data prior to reconciliation. We appreciate the support and suggestions for our efforts to improve both the utility of MA encounter data and support of State requirements for quality reporting. We will consider comments and suggestions received as we move forward.

T. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process

In this final rule, we are revising certain timing issues in terms of when RADV medical record review determination and payment error calculation appeals can be requested and adjudicated. Specifically, we proposed that Medicare Advantage (MA) organizations must exhaust all levels of appeal for medical record review determinations before the payment error calculation appeals process can begin. We believed that this clarification was necessary because RADV payment error calculations are directly based upon the outcomes of medical record review determinations. We also proposed several other changes to our regulatory appeals process to conform with these proposed revisions.

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries, and that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MA organizations also ensures we are safeguarding Federal taxpayer dollars.

Contract-level RADV audits are CMS's main corrective action for overpayments made to MA organizations when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. CMS conducts RADV audits of MA organization-submitted diagnosis data from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. CMS can collect the improper payments identified during CMS and Department of Health and Human Services Office of Inspector General (HHS–OIG) audits, including the extrapolated amounts calculated by the OIG. The RADV audit appeals process, as outlined in 42 CFR 422.311, is applicable to both CMS and HHS–OIG audits and is therefore referred to as the ''MA RADV audit appeals process.'' Additional information regarding CMS's contract level RADV audits was outlined in the RADV final rule, CMS–4185–F2, published on February 1, 2023.[76]

1. Current MA RADV Appeals Process

CMS previously established a process after notice and comment rulemaking for MA organizations to appeal RADV audit findings as outlined by provisions at 42 CFR 422.311(c)(6)–(c)(8). Once review of the medical records submitted by MA organizations to support audited HCCs is completed and overpayment amounts are calculated, HHS (CMS or HHS–OIG) issues an audit report to each audited MA organization contract. In accordance with § 422.311(b)(1), this audit report includes the following:

- Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.
- The contract-level RADV-payment error estimate in dollars.
- The contract-level payment adjustment amount to be made in dollars.
- An approximate timeframe for the payment adjustment.
- A description of the MA organization's RADV audit appeal rights.

The MA RADV audit appeals process begins once MA organizations are notified of their audit findings via a RADV audit report. MA organizations have 60 days from the date of issuance of a RADV audit report to file a written request for appeal and must follow the Secretary's RADV audit appeals procedures and requirements under § 422.311. MA organizations may appeal RADV medical record review determinations and/or the MA RADV payment error calculation and must specify which findings the MA organization is appealing when requesting an appeal of a RADV audit finding.

Under CMS's existing RADV audit appeals regulations under 42 CFR 422.311(c)(6)–(8), the MA RADV administrative audit appeals process consists of three levels: reconsideration, hearing, and CMS Administrator review. Below is a summary of the three levels of appeal for background information only. This regulation is not revising the basic structure of these three levels of appeal.

a. Reconsideration

Reconsideration is the first stage of the RADV audit appeals process. When appealing a medical record review determination, the MA organization's written request must specify the audited HCC(s) that it wishes to appeal and provide a justification of why the audited HCC(s) should not have been identified as an error. When appealing a payment error calculation, the MA organization's written request must include its own RADV payment error calculation that clearly indicates where HHS' payment error calculation was erroneous, as well as additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider. For payment error calculation appeals, a third-party who was not involved in the initial RADV payment error calculation reviews the HHS and MA organization's RADV payment error calculations and recalculates, as appropriate, the payment error using the appropriate payment error calculation method for the relevant audit.

The reconsideration official issues a written reconsideration decision to the MA organization, and this decision is considered final unless the MA organization disagrees with the reconsideration official's decision and submits a valid request for CMS hearing officer review. A new audit report is

[76] *https://www.federalregister.gov/documents/2023/02/01/2023-01942/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

subsequently issued for either a medical record review determination reconsideration or a payment error calculation reconsideration only if the reconsideration official's decision is considered final.

b. Hearing Officer Review

An MA organization that disagrees with the reconsideration decision may request a hearing officer review in accordance with procedures and timeframes established by CMS under 42 CFR 422.311(c)(7). If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official, specify the audited HCC(s) that the reconsideration official confirmed as being in error, and explain why the MA organization disputes the reconsideration official's determination. If the MA organization appeals a RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and the MA organization's RADV payment error calculation that clearly specifies where the MA organization believes the Secretary's payment error calculation was erroneous.

The hearing officer has the authority to decide whether to uphold or overturn the reconsideration official's decision and, pursuant to this decision, sends a written determination to CMS and the MA organization explaining the basis for the decision. If necessary, a third party who was not involved in the initial RADV payment error calculation recalculates the RADV payment error and issues a new RADV audit report to the MA organization. For MA organizations appealing the RADV payment error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS. The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

c. CMS Administrator Review

Under the existing RADV audit appeals regulation at 42 CFR 422.311(c)(8), a request for CMS Administrator review must be made in writing and filed with the CMS Administrator within 60 days of receipt of the hearing officer's decision. After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision. If the CMS Administrator elects to review the hearing decision, the CMS Administrator then will acknowledge the decision to review the hearing officer's decision in writing and notify CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. The decision of the hearing officer becomes final if the CMS Administrator declines to review the hearing officer's decision or does not render a decision within 60 days.

2. Proposed Policies

In this final rule, we are revising the timing of when a medical record review determination and a payment error calculation appeal can be requested and adjudicated. Specifically, we proposed that MA organizations must exhaust all levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. We believed that this change was necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations and the current regulatory language is somewhat ambiguous regarding this point. Adjudicating medical record review determination appeals prior to payment error calculation appeals alleviates operational concerns for CMS and burden on MA organizations by preventing unnecessary appeals of payment error calculations that will be moot if revisions must be made to payment error calculations based on medical record review determination appeal decisions.

Section 422.311(c)(5)(iii) states that, ''for [MA organizations] that appeal both medical record review determination appeal and RADV payment error calculation appeal [,] (A) the Secretary adjudicates the request for the RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.'' The regulations also state that, for cases in which an MA organization requests both a medical record review determination appeal and payment error calculation appeal, ''. . . (B) an [MA organization's] request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are *final for that stage of appeal*'' [emphasis added]. This language arguably addresses both those cases in which the final adjudication is reached during the reconsideration phase, as well as those that proceed to the second and third level of appeal. We proposed to delete § 422.311(c)(5)(ii)(C), which requires MA organizations requesting both a medical record review determination appeal and payment error calculation appeal to file their written requests for both appeals within 60 days of the issuance of the RADV audit report before the reconsideration level of administrative appeal. Instead, we proposed that MA organizations may request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time. We proposed to amend § 422.311(c)(5)(iii) by providing that MA organizations who request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process.

An MA organization may also choose to only appeal the payment error calculation, and therefore, no preceding medical record review determination appeal will occur. MA organizations choosing to only file a payment error calculation appeal will not be able to file a medical record review determination appeal after the adjudication of payment error calculation appeal. At § 422.311(c)(5)(ii)(B), we proposed to specify that MA organizations will forgo their medical record review determination appeal if they choose to only file a payment error calculation appeal, because medical record review appeals decisions need to be final prior to adjudicating a payment error calculation appeal.

At § 422.311(c)(5)(iii)(A) *and (B),* we proposed to specify that this process is complete when the medical record review determination appeals process has been exhausted through the three levels of appeal, or when the MA organization does not timely request a medical record review determination appeal at the hearing officer or CMS Administrator review stage. At proposed § 422.311(c)(5)(iii)(B), we proposed that an MA organization whose medical record review determination appeal has been completed has 60 days from the issuance of a revised RADV audit report to file a written request for payment error calculation appeal, which specifies the issues with which the MA organization disagrees and the reasons for the disagreements. If, as a result of the medical record review determination appeals process, no

original determinations are reversed or changed, then the original audit report will be reissued, and the MA organization will have 60 days from the date of issuance to submit a payment error calculation appeal if it so chooses.

We also proposed to revise § 422.311(c)(6)(i)(A) to clarify that an MA organization's request for medical record review determination reconsideration must specify any and all audited HCCs from an audit report that the MA organization wishes to dispute. The intent of this revision is to permit an MA organization to submit only one medical record review determination reconsideration request per audited contract, which includes all disputed audited HCCs, given that the results of all audited HCCs for a given audited contract are communicated as part of a single audit report.

We also proposed to revise § 422.311(c)(6)(iv)(B) to clarify that the reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x).

We also proposed to add § 422.311(c)(6)(v) to clarify that the reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final in accordance with § 422.311(c)(6)(iv)(B). If the reconsideration official's decision is considered final in accordance with § 422.311(c)(6)(iv)(B), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also proposed to revise § 422.311(c)(7)(ix) to clarify that if the hearing officer's decision is considered final in accordance with § 422.311(c)(7)(x), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit. Once the medical record review determination decision of the adjudicator is final, we believe the same entity that issued the audit report will be able to revise the audit report by applying any medical record review determination findings that may have changed through the medical record review determination appeal process and issue a revised audit report in the most efficient and streamlined manner. Issuing a revised audit report is a standard process and neutrally applies the final adjudicator's medical record review determination findings. This process is consistent with other long standing CMS appeals program, such as the Provider Reimbursement Review Board (PRRB), where post-adjudication revised determinations are issued by the same entity (*e.g.,* the Medicare Administrative Contractor for PRRB cases) that issued the original determination.

- We also proposed the following to provide clarity to the Administrator's level of appeal: To revise § 422.311(c)(8)(iii) to add a requirement that if the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.
- To revise § 422.311(c)(8)(iv)(A) to clarify that CMS and the MA organization may submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision.
- To revise § 422.311(c)(8)(v) to clarify that the requirement of the Administrator to render a final decision in writing within 60 days of the issuance of the notice acknowledging the decision to elect to review the hearing officer's decision and the 60-day time period is determined by the date of the final decision being made by the Administrator, not by the date it is delivered to the parties.
- To revise § 422.311(c)(8)(vi) to clarify the scenarios in which the hearing officer's decision becomes final after a request for Administrator review has been made.
- To add new § 422.311(c)(8)(vii) that states once the Administrator's decision is considered final in accordance with § 422.311(c)(8)(vi), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also proposed to add new § 422.311(c)(9) to specify what actions related to the RADV audit appeals process constitute final agency action. Specifically, in cases when an MA organization appeals a payment error calculation subsequent to an MRRD appeal that has completed the administrative appeals process, the MRRD final decision and the payment error calculation final decision will not be considered a final agency action until the related payment error calculation appeal has completed the administrative appeals process and a final revised audit report has been issued.

We also proposed to revise § 422.311(a) to remove the word ''annually'' for clarity, as the Secretary may conduct RADV audits on differing cadences between the CMS and HHS–OIG RADV audits.

3. Summary of Public Comments

We invited public comment on these proposals and received several comments. Specifically, we received numerous comments regarding our proposals related to the timing of requesting and adjudication of MRRD and PEC appeals. We did not receive any comments specifically addressing our proposals related to the finality of decisions at each level of appeal of appeal, nor the requirements for revised or reissued audit reports. We did not receive any comments specifically addressing our proposals related to the requirements affecting the elective Administrator review process. We did not receive any comments specifically related to our proposal concerning the definition of final agency action. A discussion of these comments, along with our responses follows.

Comment: Commenters generally expressed support for our proposed policies regarding the timing of MRRD and PEC appeals. Commenters stated that these proposals will provide needed clarity in the RADV audit appeals process and that by disallowing MRRD appeals and PEC appeals from being adjudicated concurrently, we will avoid potential administrative complications. Commenters generally agreed that these changes will create uniformity and consistency in the appeals process. One commenter, in addition to supporting our proposed appeals policies, encouraged CMS to consider larger scale reforms to reduce substantial overpayments to MA organizations and recover improper payments.

Response: We thank these commenters for their support of our RADV audit program and our appeals proposals. We agree that the proposals will create uniformity and consistency, as well as avoid administrative complications in the appeals process.

Comment: A commenter requested clarification regarding whether completion of the MRRD appeals process is distinct if an MA organization does not have a medical record to review.

Response: Any valid medical record that is reviewed as part of a RADV audit and found to not substantiate the audited diagnosis may be appealed if the MA organization disagrees with the audit finding. If an MA organization does not wish to appeal any of the medical record review determinations or does not request an appeal by the deadline, the MA organization may

proceed with a PEC appeal. If the commenter is asking whether there are MRRD appeal rights when an MA organization does not submit a medical record to substantiate a diagnosis during an audit, pursuant to § 422.311(c)(3)(iv) MA organizations may not appeal RADV errors that result from failure to submit a valid medical record.

Comment: A commenter requested that we alter the proposal to support uniformity between the RADV appeals process and the OIG audit process.

Response: The RADV audit appeals provisions being finalized in this rule are applicable to appeals of RADV audit findings resulting from both CMS and OIG audits. As stated in § 422.311(a), RADV audits are conducted by the Secretary and the results of any such audit by CMS or OIG are appealable pursuant to § 422.311(c). Appeal rights to audit findings based on either CMS or OIG RADV audits begin with the issuance of an audit report that details audit findings.

4. Comments Out of Scope of the Proposed Policies

We received several comments that were beyond the scope of the proposed rule. Commenters sought additional clarification and made recommendations related to the underlying risk adjustment payment model, aspects of the RADV audit methodology related to sampling and extrapolation, and the need for monetary penalties to be applied to providers or other actors that contributed to a negative RADV finding.

We thank commenters for making broad recommendations for changes to the risk adjustment payment model and for the application of monetary penalties; however, the scope of this rule is limited to the RADV audit appeals process.

Regarding the use of extrapolation and other aspects of RADV audit methodology, the RADV audit appeals process is limited to medical record review determinations and payment error calculations communicated to MA organizations in an audit report. Pursuant to § 422.311(c)(3)(iii), the Secretary's medical record review determination methodology and payment error calculation methodology are ineligible for appeal under this process. While MA organizations may appeal individual medical record review determinations and the resulting payment error calculation, they may not appeal the underlying audit methodology.

5. Final Policy

After consideration of the public comments received, we are finalizing these policies as proposed. As noted above, we did not receive comments on some proposals and are finalizing those policies as proposed.

IV. Benefits for Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Part C and Part D Midyear Benefit Changes (§§ 422.254, 423.265)

1. Overview and Summary

In our proposed rule titled ''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,'' (*87 FR 79452*) which appeared in the December 27, 2022 issue of the **Federal Register** (hereinafter referred to as the ''December 2022 proposed rule''), we proposed two provisions that, if finalized, would restrict changes to the benefits offered by plans (inclusive of MA, MA–PD, and Part D) within the contract year.

We proposed these provisions to codify our longstanding policy prohibiting midyear benefit changes (MYBCs), previously referred to as midyear benefit enhancements (MYBEs), for MA and Part D plans. Specifically, we proposed to prohibit changes to non-drug benefits, premiums, and cost sharing by an MA organization 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 proposed to codify 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. This prohibition applies 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.

2. Medicare Advantage Prohibition on Midyear Benefit Changes (§ 422.254)

In a 2008 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,'' we prohibited MA organizations from making any midyear changes in benefits, premiums, or cost sharing, even under the circumstances in which these types of changes had been permitted previously.[77] We have enforced this policy to the present day. It is necessary to prohibit benefit changes after bids are submitted and after marketing is permitted to begin in order to maintain the integrity of the bidding process. MA organizations are still allowed to make changes during the bidding process when permitted by CMS to remain in compliance with the requirements set forth at § 422.254 and when permitted by § 422.256. 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. However, allowing MYBCs undermines the integrity of the bidding process because it would allow MA organizations to alter their benefit packages after the bidding process is complete. Finally, 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 enrolling newly age-eligible enrollees is attractive to MA organizations because of their relatively low health care utilization, as these individuals tend to be healthier compared to older beneficiaries (*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

[77] HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency, *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

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 July 2008 final rule, we have continued to receive inquiries from MA organizations requesting changes to PBPs after the contract year has begun.

We also noted in the December 2022 proposed rule that CMS has interpreted MYBCs after the start of the contract year to violate the uniformity requirements set forth at § 422.100(d)(ii), which require that an MA organization must offer a 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, because some enrollees would have paid for such benefits, premiums, or cost sharing already, and might 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 plan enrollees who paid depending on when the MYBC was put in effect.

Furthermore, we noted in the December 2022 proposed rule that 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. We stated that these EGWPs are not currently subject to this prohibition on MYBCs under existing CMS waivers for EGWPs and will not be subject to the new regulation prohibiting MYBCs. However, we stated, an MA organization is subject to the prohibition on MYBCs if the MA organization offers an MA plan 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*.)

We proposed to add new paragraph § 422.254(a)(5) explicitly prohibiting MYBCs and specifying when this prohibition applies. Specifically, we proposed 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, except for modifications in benefits required by law.

3. Part D Prohibition on Midyear Benefit Changes (§ 423.265)

In the December 2022 proposed rule (*87 FR 79452*), we proposed to add new paragraph § 423.265(b)(5), which states that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), it may not change the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182(a)) for the contract year, except where a modification in benefits is required by law.

In part, section 1860D–11(e)(2)(C) of the Act, codified at § 423.272(b)(1), requires that CMS may only approve a bid if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan. MYBCs indicate that the plan bid was overstated and render the bid meaningless, while 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. In our final rule titled ''Medicare Program; Medicare Prescription Drug Benefit'' (*70 FR 4194*), which appeared in the January 28, 2005 issue of the **Federal Register** (hereinafter referred to as the ''January 2005 Part D final rule''), we stated in the preamble 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 changes, as these 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*). In other words, waiving or reducing the premiums and/or cost sharing that are reflected in the approved bid would indicate that the amounts provided in the bid do not reasonably and equitably reflect the revenue requirements of the expected population for the plans' benefits as required.

In the December 2022 proposed rule, we drew a distinction 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). Section 1860D–4(b)(3)(E) of the Act, as codified at § 423.120(b)(5), 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). However, CMS has 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 associated with an entire tier of drugs), or cost sharing (for all or individual enrollees) once plans are permitted to market for the following contract year (on October 1, now reflected in § 423.2263(a)) on the grounds that such activities would be inconsistent with the CMS-approved bid.

As we noted 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''), a Part D sponsor's waiver of cost sharing midyear violates the uniform benefit requirements because such a waiver 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 at midyear because that would violate the uniform benefit provisions set forth in § 423.104(b). Even if the plan changed the benefit midyear for all of the plan's enrollees, this would still violate the uniform benefit provision because some of the plan's enrollees would still have paid for benefits prior to the change. For example, because drug costs are often not evenly distributed over the course of a year, a midyear reduction in cost sharing could provide unequal benefit to enrollees who had the same drug costs but in different phases of their Part D benefit.

We received the following comments on the proposed Medicare Advantage and Part D prohibitions on midyear changes to be added at §§ 422.254 and 423.265, and our responses follow:

Comment: Most of the comments received discussed midyear benefit changes broadly, without specific reference to the MA or Part D provisions. Most commenters took a positive or neutral stance on the two proposals, but a few were opposed to them. A commenter asked that CMS allow midyear benefit changes when plans attempt to improve their benefit packages. Another commenter stated that CMS should make an exception when new products are released to market, particularly pointing to new drugs that receive FDA approval.

Response: As discussed in the proposed rule, changes in bid-level cost sharing or benefits after bids have been submitted could undermine the integrity of the bidding system, disincentivize plans from submitting complete and accurate bids on time, provide competitive advantages to plans that make such changes, undermine CMS's ability to provide accurate comparative information to beneficiaries about plan benefits and costs, and potentially violate the uniform benefit requirements. Both the MA and Part D bid submissions rely on applying a consistent set of criteria for evaluating the suitability and reasonableness of an MA organization or Part D sponsor's estimated costs for the contract year. Allowing plans to make benefit changes after the bid submission deadline would compromise the integrity of that process by introducing new variation between the costs estimated at the bid submission deadline and the actual costs incurred. A sophisticated MA organization or Part D sponsor may attempt to analyze their population during the contract year and determine which benefit changes could improve their overall costs, causing their bid projections to be distorted relative to a different organization or plan sponsor's bids and costs. Similarly, an organization or plan sponsor that sees lower than expected membership could try to adjust their benefits within the year to be more enticing. They may decide, with the availability of the contract year emerging experience, to change their competitive position by adjusting benefits. This would be inconsistent with the standardized bidding process set forth in statute and regulation, which requires plans to bid using only the information available to them at that time. The bid process ensures that MA organizations and Part D sponsors are assuming the risk for the contract year on an equitable basis and receiving fair reimbursement for that risk.

In addition, the potential distortion between the bid amounts and the actual costs after a mid-year benefit change could reduce the accuracy of information based on the bids that is released by CMS. For example, if Part D sponsors are making changes during the contract year that would have resulted in higher bids, that would mean that the release of the national average monthly bid amount is artificially low. This, in turn, would mean that all downstream payments relying on the national average would be inaccurate as well.

The proposed regulatory provisions would restrict changes to the fundamental aspects of plan benefit package design. Under our proposal, MA plans would not be prohibited from making adjustments to their own rules on such matters as prior authorization or referral policies, or from making changes to their provider network, so long as these adjustments or network changes remain within the bounds of existing regulatory requirements and are consistent with the approved plan benefit package. *See,* for example, § 422.111(d) and (e). Likewise, Part D plans would continue to be allowed to make midyear formulary changes that result in cost sharing changes for individual drugs, but they would not be allowed to change cost sharing for entire tiers of drugs or adjust premiums.

In addition, we clarify that the prohibition on MYBCs, which has been longstanding CMS policy, does not and will not prohibit Part D plans (including MA–PD plans) from enhancing their formularies to add coverage of new FDA-approved products. Section 1860D–4(b)(3)(C)(iii) of the Act (echoed in regulation at § 423.120(b)(4)) specifically allows an exception to the rules prohibiting changes to the therapeutic classes and categories of a formulary in order ''to take into account new therapeutic uses and newly approved covered Part D drugs.'' Nothing in our proposed policy overrides the statutory requirement or the equivalent language in existing regulation. In addition, because MA plans must cover all Part A and Part B benefits (subject to limited exclusions as outlined at § 422.100(c)), changes in items and services covered under Parts A and B due to changes in the law, new or changed NCDs, and advances in medical technology or new healthcare services that are newly covered by Traditional Medicare under existing benefit rules must be covered for MA enrollees as well. See § 422.109 for more information on how NCD and legislative changes in benefits are incorporated into the coverage for MA enrollees.

Comment: Some commenters indicated that they appreciated a number of the waivers and flexibilities pertinent to midyear changes that CMS implemented during the COVID–19 public health emergency. One commenter highlighted several of the pharmacy access and cost-sharing flexibilities as particularly helpful in the midst of the emergency. The commenters who expressed appreciation for the COVID–19 waivers and flexibilities also requested that CMS extend those flexibilities through the end of 2023 to allow plans time to transition.

Response: We thank the commenters for providing their input. The waivers and flexibilities for which these commenters requested extensions ended with the conclusion of the Public Health Emergency on May 11, 2023.[78] We do not believe it is necessary or appropriate to continue those flexibilities outside of the context of the PHE. As discussed in the proposed rule (*87 FR 79514 through 79517*) and in the prior response, there are important policy considerations and statutory compliance issues served by the prohibition on MYBCs.

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the proposed new provisions at §§ 422.254(a)(5) and 423.265(b)(5) without substantive modification. We have made minor modifications to clarify the text.

[78] HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency, *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

AA. Failure To Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§ 423.293 and 423.294)

In the December 2022 proposed rule *(87 FR 79452),* we proposed requirements for Part D sponsors to: (1) refund incorrect collections of premiums and cost sharing, and (2) recover underpayments of premiums and cost sharing. We also proposed to establish both a lookback period and timeframe to complete overpayments and underpayment notices, as well as a de minimis threshold for associated refunds and recoveries. We solicited comments regarding the addition of similar requirements in MA, specifically regarding establishing a lookback period and de minimis threshold for refunding incorrect collections.

Part D sponsors' failure to attempt to collect cost sharing or premiums is a violation of statutory and regulatory requirements. Part D sponsors' incorrectly high or low collections of cost sharing and premiums would have the effect of making the benefit non-uniform and would violate the uniform premium and benefit requirements of section 1860D–2(a) of the Act and § 423.104(b). Existing language at § 423.104(b) mirrors the language at § 422.100(d)(1) and (2)(i) with regard to uniform premiums and cost sharing. Similarly, whether done in a small number of instances or to all members enrolled of a plan, the excess collection of premiums is the basis for intermediate sanctions, as stated in section 1857(g)(1)(B) of the Act, covering Medicare Advantage organizations, and 1860–12(b)(3)(E), for Part D sponsors. However, although CMS adopted a regulation for the MA program at § 422.270 to address incorrect collections of premiums and cost sharing in the final rule titled ''Medicare Program; Establishment of the Medicare Advantage Program'' (*70 FR 4640*), which appeared in the **Federal Register** on January 28, 2005, the regulations in Part 423 have not previously addressed Part D sponsor requirements regarding incorrect collections of premiums and cost sharing. In the December 2022 proposed rule, we proposed to add a new regulation at § 423.294 to establish new Part D requirements that generally align with the existing MA requirements in § 422.270 for incorrect collections and to establish new Part D requirements regarding failure to collect premiums and cost sharing amounts.

Specifically, in order to align Part D with the existing MA requirements in § 422.270 we proposed to add a new regulation at § 423.294, which at paragraph (c) 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 same 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. We also proposed to add new § 423.294(b)(2) to require a Part D sponsor to 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).

In addition, we proposed new Part D requirements for the management of incorrect collections. First, we proposed 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. Part D sponsors have been required to process retroactive claims adjustments within 45 days of receiving complete information, per § 423.466(a), but there has been no requirement for the timing of retroactive premium adjustments. Although § 423.466(b) allows 3 years for coordination of benefits, there was no limit in the regulation for how far back a Part D sponsor must look to determine whether 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 far back as seven years ago. This is not only inconsistent with our coordination of benefits requirements, which only require adjustments for the past 3 years, but is potentially confusing to beneficiaries. By establishing 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. This 3-year period coincides with the timeframe established in § 423.466(b) for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs), other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf. A Part D sponsor would not be required to make a premium or claims payment adjustment if more than 3 years have passed from the date of service, just as a Part D sponsor is required to coordinate benefits for a period of 3 years.

Second, we proposed in §§ 423.294(b)(2) and (4) and 423.294(c)(2), respectively, 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 the timeframes for claims adjustments, 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 and/or cost sharing, or recovery of underpayments of premiums and/or cost sharing, 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.

Finally, we proposed to apply a de minimis amount, calculated per Prescription Drug Event (PDE) transaction for cost sharing or, for premium adjustments, per month, for these refunds and recoveries. Specifically, we proposed in § 423.294(b) and (c)(1) that if a refund or recovery amount falls below the de minimis amount set for purposes of § 423.34(c)(2) for the low-income subsidy (currently set at $2), the Part D sponsor would not be required to issue a refund or recovery notice. For example, if a plan sponsor in 2025 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 2025 is $2, the sponsor would not have to issue recovery notices to any beneficiary who owed $24 or less for the 12-month period.

The proposed rule preamble also noted that we are not making 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 are treated as revenue and are included in the MLR denominator.

In addition, the proposed rule noted that current MA regulations set forth at § 422.270 do not contain allowances for de minimis amounts or limits to the lookback periods for MA organizations to refund or recover incorrect collections of cost sharing or premiums. 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) provides that an enrollee may make payments in equal monthly installments 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. In the proposed rule, we solicited comments on adding requirements regarding a de minimis amount and lookback periods for recovering or refunding incorrect collections in MA that would mirror the proposed requirements in Part D.

We also proposed to implement a technical change to existing regulation text related to the Part D retroactive collection of monthly beneficiary premiums. Specifically, we proposed 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 received comments in response to the proposed new regulatory text at §§ 423.293 and 423.294. A summary of the comments received and our responses follow.

Comment: A commenter stated that the collection of cost sharing is materially different from premium collection and stated that CMS should not proceed with the proposal to codify the collection of cost sharing and premiums together under § 423.294. They noted that premiums are collected by the plans, but collection of cost sharing is managed by pharmacies and should not be described as the plans' responsibility. This commenter believed it was inappropriate for the proposal codifying our interpretation of the uniform benefit requirement to include cost sharing because plans are not the parties that fail to collect beneficiary cost sharing. The commenter stated that plans would only have control over cost sharing in the case of retroactive adjustments and asked that the provision be revised to either explicitly state that the requirement only applies to plans in the case of retroactive adjustments, or to exclude language regarding cost sharing.

Response: We recognize that there is a fundamental difference between the collection of Part D cost sharing and premiums under normal circumstances. Pharmacies, not plans, collect cost sharing at the point of sale, and therefore plan oversight of cost sharing is more resource intensive in the case of retroactive adjustments. Pharmacies may also have certain autonomy when it comes to the collection of cost sharing. Pharmacies, as outlined at § 1001.952(k)(3), may choose to waive cost sharing under specific, but limited, circumstances (for example, in the circumstances outlined at 42 CFR § 1001.952(k)(3)). With those limitations in mind, the preamble of the December 2022 proposed rule *(87 FR 79517)* makes clear that we anticipate retroactive adjustments to be the primary circumstance in which plans will handle cost sharing directly.

However, the uniform benefit requirement at § 423.104(b)(2) requires Part D plan sponsors to offer ''a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area.'' As noted in the October 2009 proposed rule *(74 FR 54690),* CMS has consistently interpreted the uniform benefit requirement to prohibit Part D sponsors from varying cost sharing and premiums within its service area. While plan sponsors will primarily manage cost sharing directly in the case of retroactive adjustments, our existing regulations have placed significant responsibility for the correct collection of cost sharing on plan sponsors. For example, plans may exercise authority through their network participation agreements to define pharmacies' responsibility to collect cost sharing, per regulations at § 423.104(g). The proposed regulation merely codifies a portion of the obligations that plans have already been required to uphold.

Comment: A commenter stated that the proposed 3-year lookback period for incorrect collections does not align with the six-year overpayment lookback period. They proposed that CMS should revise the proposed provision to clarify that it would only require plan sponsors to refund or collect cost sharing created through retroactive adjustments. Alternatively, they asked CMS to clarify whether CMS would adjust its payments to plans outside of the 3-year lookback period but refuse to allow plans to initiate reimbursements or recoveries in that same period.

Response: While the commenter is correct that the proposed lookback period for incorrect collections would not align with the six-year overpayment lookback period (defined in regulation at § 423.360(f)), it was not our intention to align these lookback periods. It was our stated goal to clarify that the lookback period for Part D incorrect collections should be understood as covered by the lookback period outlined in regulation for coordination of benefits (at § 423.466(b)). While the overpayment lookback period in § 423.360(f) pertains to the reporting and returning of CMS overpayments by plans, our proposed incorrect collections provision better aligns with other aspects of coordination of benefits that are relevant to beneficiary or third-party payments to plans and pharmacies. For example, CMS payments to plans and the associated plan payment reconciliation processes are not closely related to the repayment to, or recovery of funds from, individuals. The incorrect collection of cost sharing and the adjustments that can be made in the coordination of benefits process, however, are inherently related. Furthermore, while the provision does not require plans to provide adjustments beyond the 3-year lookback window, there is nothing that would prohibit plans from voluntarily issuing refunds for premium or cost sharing overpayments, so long as they did so in a uniform manner.

Comment: A commenter stated that they were opposed to the 45-day timeframe for processing refunds and recoveries for premium adjustments proposed at § 423.294(b)(2). Because the adjustment process can be complicated, they indicated that a 90-day timeframe would be preferable instead.

Response: First, we note that the 45-day timeframe is meant for the beneficiary's benefit and is not related to record keeping. Furthermore, as stated in the December 2022 proposed rule *(87 FR 79517),* we are aligning the adjustment of retroactive premium adjustments with the timeline for processing retroactive claims adjustments. Part D sponsors are already required to process retroactive claims adjustments within 45 days of receiving

complete information, per § 423.466(a), and the proposal would simply impose a similar requirement for premium adjustments. While the process for refunding or recovering premiums may be complicated, we do not consider it to be substantially more complicated than final processing of retroactive claims adjustments. Furthermore, as noted earlier in this section, plan sponsors are already required to make claims adjustments for refunds and recoveries related to the low-income subsidy program within a 45-day window (per § 423.800(e)). Finally, we also believe it to be in the beneficiary's interest to resolve refunds and recoveries in a timely manner. As explained, the 45-day window has been used for adjustments in the past, and we consider it to be still most appropriate in this circumstance.

Comment: Commenters were divided in their opinions of the proposed de minimis amount for incorrect collections of Part D premiums and cost sharing. While some commenters were supportive, others expressed opposition to the proposal. A commenter suggested that the proposed de minimis regulation could be interpreted to be optional, but they argued that it should be made mandatory across all plans in order to prevent enrollee confusion. Another commenter suggested that the proposal, which they understood to be mandatory, would deprive plans of existing flexibility to determine on their own the financial thresholds that are appropriate for collection.

Response: We clarify that CMS has not previously provided Part D sponsors with flexibility to pursue or return incorrect collections only when they deem the funds sufficient to be worth the time and effort. As noted in the October 2009 proposed rule *(74 FR 54690),* CMS has interpreted a failure to attempt to collect premiums and cost-sharing as a violation of the uniform benefit requirement. Plans are already required to ensure correct payment of premiums and cost-sharing, consistent with current regulations and guidance, which do not define a minimum amount below which the obligation to provide a refund to enrollees (or to collect from enrollees) does not apply. We proposed and are finalizing at § 423.294(b) and (c)(1) that it is not mandatory for Part D sponsors to collect or refund amounts below the de minimis threshold established in the regulation.

Furthermore, there will be little financial difference to enrollees whether plans adopt the de minimis requirement or continue to refund or recover all incorrectly collected amounts. For instance, the de minimis amount for premium adjustments for 2024 will amount to $2 per month. Thus, under the proposed rule, plans would only be permitted to forego premium adjustments less than or equal to $24 for a calendar year. In the case of one-time errors or errors that took place over a small number of instances, the amounts involved may be less than the postage required to send a refund or recovery notice to a beneficiary. In combination with the 3-year lookback period, we believe that our proposed de minimis amount provision would enable plans to minimize their own burden while also limiting beneficiary confusion over minor adjustments to previously paid premiums and cost-sharing.

Comment: A commenter requested clarification regarding whether recoupment of underpayments will apply to dually eligible beneficiaries, noting that the dually eligible population often faces obstacles that limit their ability to make unexpected payments. The commenter also stated their belief that CMS had not previously required Part D sponsors to attempt to recover underpayments of premiums and cost-sharing and refund overpayments.

Response: Under current regulations and guidance, plan sponsors are already required to recover underpayments and refund overpayments, regardless of the amount. Our proposal elaborated on existing regulations applying to incorrect collections of premiums and cost sharing. As explained in the October 2009 proposed rule *(74 FR 54690)* and reiterated here, we have interpreted failure to attempt to collect premiums and cost sharing as a violation of the existing uniform benefit requirement at § 423.104(b). In addition, there is at present no clear limit to the lookback period for premium and cost-sharing adjustments. While our proposed policy would apply to dually eligible enrollees, the abbreviation of the lookback period and inclusion of de minimis amount regulation may serve to decrease the frequency with which plans attempt to recover incorrect collections from dually eligible enrollees. Existing regulation and guidance provide further protections for dually eligible enrollees. In the case of retroactive premium collections in which the enrollee is without fault, § 423.293(a)(4) instructs sponsors to offer the enrollee the opportunity to make payment by lump sum, by equal monthly installments spread out over at least the same period over which the payments were due, or through other arrangements mutually acceptable to the enrollee and the sponsor Similar recommendations can be found in section 70.3.1 of Chapter 13 of the Prescription Drug Benefit Manual, which covers refunds and recoupments for the premium and cost-sharing subsidies for low-income individuals and would apply to all full dually eligible enrollees and individuals eligible for a Medicare Savings Program as a Qualified Medicare Beneficiary, Specified Low Income Medicare Beneficiary, or a Qualifying Individual.

Comment: A commenter responded to CMS's request for feedback about aligning elements of the process for MA incorrect collections with those in the December 2022 proposed rule *(87 FR 79517)* for Part D. The commenter believed that the process for collecting cost sharing is more complex for MA plans than for Part D plans. The lag in payments and collections involved in, for example, clinical and hospital visits necessitates substantial differences between the incorrect collections policies of the two programs.

Response: We appreciate the commenter's feedback. We decline to revise § 422.270 at this time to: (1) apply a threshold for a de minimis amount below which refunds of excess MA cost sharing or excess MA premiums are not required, or (2) adopt lookback periods to limit the obligation for MA organizations to recover or refund incorrect collections of such payments. We may revisit these policies for the MA program at a later date.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to §§ 423.293 and 423.294 as proposed with minor grammatical and formatting changes.

B. Definition of ''Basic Benefits'' (§ 422.2)

Section 1852(a)(1)(B)(i) of the Act defines the term ''benefits under the original Medicare Fee-for-Service program option'' for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide enrollees such benefits. Section 17006(c)(1) of the 21st Century Cures Act (Pub. L. 114–255) (hereafter referred to as ''the Cures Act'') amended section 1852(a)(1)(B)(i) of the Act by inserting ''or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)'' after ''hospice care.'' Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans no longer cover organ acquisitions for kidney transplants, including the costs for

living donors covered by Medicare pursuant to section 1881(d) of the Act.

In the April 2019 final rule [79] and the January 2021 final rule, we amended the definition of ''basic benefits'' at § 422.100(c)(1) to exclude coverage for organ acquisitions for kidney transplants, effective beginning in 2021, in addition to the existing exclusion for hospice care. In the June 2020 final rule, we also amended several regulations to address coverage of organ acquisition for kidney transplants for MA enrollees, with amendments to §§ 422.258, 422.322, and 422.306. However, we inadvertently omitted making the same type of revision to the ''basic benefits'' definition at § 422.2. We proposed to correct the definition of basic benefits at § 422.2 to add the exclusion of coverage for organ acquisitions for kidney transplants to § 422.2.

Specifically, we proposed to revise the ''basic benefits'' definition at § 422.2 to change the phrase ''all Medicare-covered benefits'' to ''Part A and Part B benefits'' and correct the phrase ''(except hospice services)'' to include, beginning in 2021, organ acquisitions for kidney transplants (which includes costs covered under section 1881(d) of the Act).

This provision is a technical change to align the definition of basic benefits with existing law; therefore, neither an economic impact beyond current operating expenses nor an associated paperwork burden are expected.

We invited public comment on this proposal and received a comment in support of our proposal and an out-of-scope comment. We thank the commenter for their support.

For the reasons outlined in the proposed rule and summarized in this rule, we finalize the revisions to the definition of basic benefits at § 422.2 as proposed.

C. Standards for Determining Whether Special Supplemental Benefits for the Chronically Ill (SSBCI) Have a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee

The Balanced Budget Act (BBA) of 2018 included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans. We addressed these new supplemental benefits extensively 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 (hereafter referred to as ''June 2020 final rule'') (85 FR 33796, 33800–05), where we referred to them as Special Supplemental Benefits for the Chronically Ill (SSBCI).

As we summarized in the June 2020 final rule, we interpreted the intent of this new category of supplemental benefits as enabling MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for chronically ill enrollees who meet the definition established by the statute. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes the Secretary to waive the uniformity requirements generally applicable to the benefits covered by MA plans with respect to SSBCI. Therefore, CMS may allow MA plans to offer SSBCI that are not uniform across the entire population of chronically ill enrollees in the plans but that are tailored and covered for an individual enrollee's specific medical condition and needs (83 FR 16481–82).

In addition to limiting the eligibility of enrollees who can receive SSBCI to chronically ill enrollees, section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. We codified this statutory requirement as part of the definition of SSBCI at § 422.102(f)(1)(ii).

As we provided in a Health Plan Management System (HPMS) memorandum dated April 24, 2019 [80] (''2019 HPMS memo'' hereafter), SSBCI can be in the form of:

- Reduced cost sharing for Medicare-covered benefits;
- Reduced cost sharing for primarily health-related supplemental benefits;
- Additional primarily health-related supplemental benefits; and/or
- Non-primarily health-related supplemental benefits.

As we described in the November 2023 proposed rule, to offer an item or service as an SSBCI to an enrollee, an MA plan must make at least two separate determinations with respect to that enrollee in order to satisfy the statutory and regulatory requirements for these benefits. First, the MA plan must determine that an enrollee meets the definition of ''chronically ill enrollee.'' Section 1852(a)(3)(D)(iii) of the Act defines ''chronically ill enrollee'' as an individual enrolled in the MA plan who meets all of the following: (I) has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (II) has a high risk of hospitalization or other adverse health outcomes; and (III) requires intensive care coordination. Per § 422.102(f)(1)(i)(B), CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life-threatening or significantly limit the overall health or function of an individual. This list is currently the same as the list of chronic conditions for which MA organizations may offer chronic condition special needs plans, which can be found in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual. We require, currently at § 422.102(f)(3)(i), the MA plan to have written policies for making this determination and to document each determination that an enrollee is a chronically ill enrollee. Documentation of this determination must be available to CMS upon request according to § 422.102(f)(3)(ii) (to be redesignated to § 422.102(f)(4)(ii)).

Second, the MA plan must determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Currently § 422.102(f)(3)(iii) provides that the MA plan ''must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria.'' We also require the MA plan to document ''each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request'' at § 422.102(f)(3)(iv). (See later in this section for how paragraph (f)(3) of § 422.102 is redesignated and revised in this final rule.)

We noted in the November 2023 proposed rule that we do not define or definitively interpret the phrase ''has a reasonable expectation of improving or maintaining the health or overall function of the enrollee'' in regulation or policy guidance. Rather, in the 2019 HPMS memo, we provided MA plans with ''broad discretion in determining what may be considered 'a reasonable expectation' when choosing to offer specific items and services as SSBCI.'' We stated that we granted MA plans this discretion so that they might effectively tailor their SSBCI offerings and the eligibility standards for those offerings to the specific chronically ill population upon which the plan is focusing.

[79] ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' final rule (84 FR 15680).

[80] ''Implementing Supplemental Benefits for Chronically Ill Enrollees'' *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/supplemental_benefits_chronically_ill_hpms_042419.pdf* (April 24, 2019).

We further indicated that ''CMS will provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it does not have a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.'' In other words, we placed the burden on CMS, and not the MA plan, to generate evidence demonstrating whether the ''reasonable expectation'' standard—a standard that we granted broad discretion for an MA plan to determine—has been met (or not met) when offering items or services as SSBCI.

As we described in the November 2023 proposed rule, supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars.[81] When submitting an annual bid to participate in the MA program, an MA organization includes in its bid a Plan Benefit Package (PBP) and Bid Pricing Tool for each of its plans, where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. Since issuing the 2019 HPMS memo, the number of MA plans that offer SSBCI—and the number and scope of SSBCI offered by an individual plan—has significantly increased. We have observed these trends in reviewing PBPs from MA plans submitted in the past few years.

In the November 2023 proposed rule, we noted that based on our internal data, 101 MA plans offered a food and produce benefit in contract year 2020, while 929 MA plans were offering this as an SSBCI in contract year 2023.[82] Similarly, 88 MA plans offered transportation for non-medical needs as an SSBCI in contract year 2020. In contract year 2023, 478 MA plans were offering this as an SSBCI.[83] MA plans are also continuing to identify items or services as SSBCI that were not included as examples in the 2019 HPMS memo. When an MA plan is offering such a benefit, the plan indicates it in the PBP [84] that is submitted with its bid. The MA plan categorizes the benefit within our PBP submission system as an ''other'' SSBCI (a benefit designation within the PBP submission system) and describes the proposed new benefit in a ''free text'' field. While 51 MA plans offered an ''other'' non-primarily health-related supplemental benefit in contract year 2020, 440 plans are offering at least one ''other'' non-primarily health related SSBCI in contract year 2023—and 226 plans are offering at least two.[85]

Through SSBCI, MA organizations can design and implement benefits, including non-primarily health-related benefits, that may be able to holistically address various needs of chronically ill enrollees. We provided in the November 2023 proposed rule that, as these benefits become a more significant part of the MA program, we believe it is important to update our processes for reviewing and approving SSBCI to manage the growth and development of new SSBCI offerings, as well as to ensure compliance with the statutory requirements at section 1852(a)(3)(D). Additionally, section 1854(b)(1)(C) of the Act requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. As an increasing share of Medicare dollars is going toward MA rebates that plans are using to offer SSBCI, we believe that revising the regulation to adopt greater review and scrutiny of these benefits is important for CMS to maintain good stewardship of Medicare dollars, including the MA rebates used to pay for these benefits, and for ensuring that the SSBCI offered are consistent with applicable law and those most likely to improve or maintain the health or overall function of chronically ill enrollees. Therefore, we proposed to update our rules and processes to simultaneously ensure effective program administration and oversight, while enabling MA organizations to offer SSBCI and improve health outcomes for chronically ill enrollees.

Currently, the burden is on CMS to review SSBCI included in an MA organization's bid and determine whether sufficient evidence or data exists to demonstrate that it has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Given the growth in the quantity and type of SSBCI offerings and given the associated burden increase on CMS in reviewing and approving bids that include SSBCI, we believe that it would be more efficient for the MA organization, rather than CMS, to demonstrate that the reasonable expectation standard has been met.

When CMS provides MA organizations with broad latitude in offering items or services as SSBCI and in establishing what a ''reasonable expectation'' means for a given SSBCI, we believe that it is appropriate for the MA organization, rather than CMS, to identify supporting evidence or data to support an SSBCI and to establish compliance with the applicable law.

We proposed that an MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. As part of shifting responsibility this way, we proposed, as relevant to an MA organization that includes SSBCI in its bid, to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of ''relevant acceptable evidence'' related to the item or service the MA organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations; (3) require the MA plan to document denials of SSBCI eligibility rather than approvals; and (4) codify CMS's authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. In addition, we proposed to make a technical edit to § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. We describe each proposal in greater detail below.

First, we proposed to redesignate what is currently § 422.102(f)(3) to (f)(4), and to address, at new § 422.102(f)(3), new requirements for each MA plan that includes an item or service as SSBCI in its bid. The MA organization must be able to demonstrate, through relevant acceptable evidence, that the item or service to be offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee and must, by the date on which it submits its bid to CMS, establish a bibliography of all ''relevant acceptable evidence'' concerning the impact that the item or service has on the health or overall function of its recipient. The bibliography must be made available to CMS upon request. As part of this

[81] MA plan rebates are a portion of the amount by which the bidding benchmark or maximum MA capitation rate for a service area exceeds the plan's bid; MA plans are obligated to use the MA rebates for the purposes specified in 42 CFR 422.266: payment of supplemental benefits (including reductions in cost sharing) or reductions in Part B or Part D premiums.

[82] Taken from CMS internal data.

[83] Taken from CMS internal data.

[84] A PBP is a set of benefits for a defined MA (or Prescription Drug Plan) service area. The PBP is submitted by MA organizations and PDP sponsors to CMS for benefit analysis, marketing, and beneficiary communication purposes.

[85] Taken from internal data.

proposal, an MA organization would be required to include, for each citation in its written bibliography, a working hyperlink to or a document containing the entire source cited. This proposal would apply only to SSBCI offered in the form of additional primarily health-related supplemental benefits or SSBCI offered in the form of non-primarily health-related supplemental benefits. It would not apply to an SSBCI offered in the form of reduced cost sharing, regardless of the benefit for which it is offered. We stated that we intended to exclude from this policy supplemental benefits offered under the Value-Based Insurance Design (VBID) Model administered by the Center for Medicare and Medicaid Innovation (CMMI), unless CMMI incorporates this policy within the VBID Model.

We also proposed, in new paragraph (f)(3)(iv), that the MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request. CMS may request and use this bibliography, without limitation, during bid review to assess whether SSBCI offerings comply with regulatory requirements, or during the contract year as part of CMS's oversight activities. We noted that CMS does not intend at this time to require MA organizations to submit these bibliographies as a matter of course in submitting bids.

We proposed that the term ''relevant acceptable evidence'' would include large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service (that is proposed to be covered as an SSBCI) impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same. We further proposed that the MA plan would need to include in its bibliography all relevant acceptable evidence published within the 10 years preceding the month in which the MA plan submits its bid. Ideally, relevant acceptable evidence should include studies and other investigations specific to the chronic conditions for which the MA organization intends to target the SSBCI, but we are not proposing to make this a requirement at this time. We are concerned that relevant acceptable evidence applicable to many SSBCI will already be limited, and that requiring a bibliography be limited to only studies concerning certain chronic conditions would discourage the development of new SSBCI. Similarly, to the extent there exists sufficient relevant acceptable evidence that the item or service meets the reasonable expectation standard for a sample of a population, an MA organization may still offer an SSBCI to enrollees with a specific chronic condition even in the absence of any studies addressing the connection between an item or service and its effect on the health or overall function of individuals with that condition.

We proposed that, in the absence of publications that meet these standards, ''relevant acceptable evidence'' for purposes of the MA plan's bibliography could include case studies, federal policies or reports, and internal analyses or any other investigation of the impact that the item or service has on the health or overall function of its recipient. By ''bibliography,'' we mean a list, and not a description, of scholarly publications or other works, as we describe below.

In our April 2023 final rule, we discussed what constituted sufficiently high-quality clinical literature in the context of an MA organization establishing internal clinical criteria for certain Medicare basic benefits (88 FR 22189, 22197). We believe that those standards are also applicable for identifying ''relevant acceptable evidence'' in the context of supporting whether an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Therefore, our proposal for § 422.102(f)(3)(ii) largely tracked the language in § 422.101(b)(6) describing acceptable clinical literature for purposes of establishing internal coverage criteria, but with revisions to be specific to the context of SSBCI and the reasonable expectation standard.

As we noted in the November 2023 proposed rule, literature that CMS considers to be ''relevant acceptable evidence'' for supporting an SSBCI offering 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 a question relevant to the requirements for offering and covering SSBCI and how the MA plan will implement the coverage—such as the impact of structural home modifications on health or overall function. Literature might also include that which involves large systematic reviews or meta-analyses summarizing the literature specifically related to the subject of the SSBCI—such as meal delivery, availability of certain food or produce, or access to pest control—published in a peer-reviewed journal with clear and consistent results. Under this proposal, an MA organization would be required to cite all such available evidence in its bibliography, and not just studies that present findings that are favorable to its SSBCI offering.

We also proposed that, in the absence of literature that conforms to these standards for relevant acceptable evidence, an MA organization would be required to include in its bibliography any other investigations of the impact of the item or service which may include evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization. In this way, our proposed policy would deviate from the standard we established for the type of evidence necessary to support an MA organization's internal coverage criteria for Medicare basic benefits. We noted in our proposal that we believe this deviation is appropriate as there is relatively less research into the impact of the provision on items or services commonly offered as SSBCI on health or overall function of chronically ill individuals.

We did not propose that relevant acceptable evidence must directly address whether there is a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee with a specific chronic illness or condition (conditions that the MA plan would have identified in its PBP submission), but such materials may be more persuasive than materials that only describe the impact of certain items and services—particularly non-primarily health-related items and services—on healthier individuals or populations. Further, our proposal was limited to SSBCI offered as additional primarily health-related supplemental benefits and non-primarily health-related supplemental benefits. We did not propose to require a bibliography for SSBCI that are exclusively cost sharing reductions for Medicare-covered benefits or primarily health-related supplemental benefits, so the regulation text was limited to SSBCI that are items or services. Although we did not propose to apply this new documentation requirement to cost sharing reductions offered as SSBCI, that type of SSBCI must also meet the reasonable expectation standard to be offered as SSBCI.

We believe that this proposal for new paragraph (f)(3) (which we are finalizing without modification, as discussed in the responses to public comments in the following pages) will serve our goal of ensuring that SSBCI regulatory standards are met—specifically, that an item or service covered as an SSBCI has a reasonable expectation of improving or maintaining the health or overall

function of a chronically ill enrollee. As we explained in the November 2023 proposed rule, we expect that rigorous research like that we describe above might be limited, and that some studies may not produce results favorable to the offering of an SSBCI. However, when there are also favorable studies, the existence of such unfavorable studies does not necessarily mean that there could not be a ''reasonable expectation'' that the SSBCI would improve or maintain the health or overall function of a chronically ill enrollee. And it is not our goal that mixed results in current literature—or the lack of rigorous research at all—would reduce innovation in SSBCI offerings. We wish to continue to see MA organizations identify new ways to deliver helpful benefits to chronically ill enrollees that can address their social needs while also improving or maintain the health or overall function of these chronically ill enrollees. Our goal is to ensure that SSBCI innovation occurs in a manner that is grounded to the extent possible in research, and that MA organizations and CMS alike are tracking to the most current research relevant to SSBCI offerings. We believe this policy will continue to promote SSBCI innovation while helping to ensure that when Medicare funds are used to offer SSBCI, such offerings meet statutory requirements.

We solicited comments on our proposed requirement that an MA organization that includes an item or service as SSBCI in its bid must, by the date on which it submits its bid to CMS, establish in writing a bibliography of all relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. We also solicited comments on our definition of ''relevant acceptable evidence,'' including the specific parameters or features of studies or other resources that would be most appropriate to include in our definition. We also solicited comments on our proposal that, for each citation in the written bibliography, the MA organization would be required to include a working hyperlink to or a document containing the entire source cited. Additionally, we solicited comments on whether we should apply this requirement to all items or services offered as SSBCI, or whether there are certain types or categories of SSBCI for which this requirement should not apply. We address comments received and our responses at the end of this section.

Second, for clarity, we proposed to explicitly require at redesignated § 422.102(f)(4)(iii) that an MA plan apply its written policies, which must be based on objective criteria, that it establishes for determining whether an enrollee is eligible to receive an SSBCI. The regulation currently requires MA organizations to have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria. While we anticipate that MA plans are already applying their written policies that identify the eligibility criteria when making these determinations, we proposed to make clear that an MA plan must apply its written policies when making SSBCI eligibility determinations.

We stated that we were considering whether to exclude the policies required by current § 422.102(f)(3) (that is, the requirements we are proposing to redesignate to new paragraph (f)(4)) from the general rule reflected in § 422.111(d) that MA plans may change plan rules during the year so long as notice is provided to enrollees. We solicited comments on whether CMS should permit changes in SSBCI eligibility policies during the coverage year, and, if so, the limitations or flexibilities that CMS should implement that would still allow CMS to provide effective oversight over SSBCI offerings. As we explained in our proposal, the ability to change plan rules during the year does not permit changes in benefit coverage but would include policies like utilization management requirements, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations.

Third, we proposed to amend redesignated paragraph (f)(4)(iv) to require that an MA plan document each instance wherein the plan determines that an enrollee is ineligible to receive an SSBCI. Denials of coverage when an enrollee requests an SSBCI are organization determinations subject to the rules in Subpart M, including the requirements related to the timing and content of denial notices in § 422.568. By fully documenting denials as required by this proposal, MA organizations should be better placed to address any appeals, including when an adverse reconsideration must be sent to the independent review entity for review. Similarly, requiring robust documentation of denials of SSBCI by MA organizations will make oversight and monitoring by CMS easier and more productive, should CMS request documentation.

We solicited comments on our proposal to require an MA plan to document its findings that a chronically ill enrollee is ineligible, rather than eligible, for an SSBCI.

Fourth, we proposed to add § 422.102(f)(5) to codify CMS's authority to decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. We clarified that while this proposal would establish a specific basis on which CMS may decline to approve an MA organization's bid, our authority to enforce compliance with other regulations and to negotiate bids (see section 1854(a) of the Act and Subpart F) would not be limited by this provision. As described in section 1854(a)(5)(C) of the Act, CMS is not obligated to accept any or every bid submitted by an MA organization, and CMS may reject bids that propose significant increases in cost sharing or decreases in benefits offered under the plan. Similarly, CMS's authority to review benefits to ensure non-discrimination is not limited or affected under this proposal. Our proposal was intended to clarify and establish that CMS's review of bids that include SSBCI could include specific evaluation of SSBCI and that CMS may decline to approve bids based on a lack of relevant acceptable evidence in support of the SSBCI offering the MA organization includes in its bid.

We also proposed to codify that, regardless of whether an SSBCI offering was approved in the past, CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, considering the relevant acceptable evidence applicable to each item or service at the time the bid is submitted. Under this proposal, CMS would have clear authority to evaluate an SSBCI included in a bid each year based on the evidence available at that time. CMS would not be bound to approve a bid that contains a certain SSBCI only because CMS approved a bid with the same SSBCI in the past. We believe this provision, if finalized, would help ensure sound use of Medicare dollars by establishing a clear connection between an SSBCI and the most current evidence addressing whether there is a reasonable expectation that the SSBCI will improve or maintain the health or overall function of a chronically ill enrollee.

We believe that codifying that CMS may decline to approve a bid for an MA

organization to offer certain SSBCI is appropriate to support CMS's programmatic oversight function. CMS already possesses the authority to negotiate and reject bids under Section 1854 of the Act, and to establish certain minimum requirements related to SSBCI under Section 1852 of the Act. We can rely on these bases as well as the requirements for SSBCI in the statute and regulations to decline to approve bids that include SSBCI that lack evidence to support the MA organization's expectations related to the SSBCI, but, as we noted in the November 2023 proposed rule, we believe it prudent to establish clearly how our evaluation of individual SSBCI offerings and the evidence supporting these offerings fit within our bid negotiation and approval authority. We believe that SSBCI provide a critical source of innovation, and we wish to see MA organizations continue to develop impactful benefits tailored to their chronically ill enrollees. However, we must also ensure that benefits offered within the MA program comply with all applicable statutory and regulatory standards. We believe it is critical for effective program administration that CMS be able to obtain, upon request, relevant acceptable evidence from an MA organization to support CMS's review of SSBCI each year considering the information and evidence available at that point in time.

We solicited comment on this proposal to codify CMS's authority to decline to approve an MA organization's bid if the MA organization fails to demonstrate, through relevant acceptable evidence, that an SSBCI included in the bid has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

The policies proposed in this section, which we are finalizing with modifications detailed further below, will work together to place the burden of showing whether an item or service offered as SSBCI has a reasonable expectation of improving the health or overall function of a chronically ill enrollee onto the MA organization. Implementing these proposals changes the policy set forth in the 2019 HPMS memo requiring CMS to provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it has not met the reasonable expectation standard. Under these proposals, the MA organization must, in advance of including an SSBCI in its bid, have already conducted research on the evidence establishing a reasonable expectation that the item or service would improve or maintain the health or overall function of the recipient of the item or service. By the time the MA organization submits its bid, it must be able to show CMS, upon request, the relevant applicable evidence that supports the reasonable expectation that the item or service would improve or maintain the health or overall function of the chronically ill enrollees it is targeting. We expect that MA plans are already proactively conducting similar research and establishing written policies for implementing SSBCI based on this research when designing them. Additionally, MA plans may seek guidance from CMS regarding SSBCI items or services not defined in the PBP or in previous CMS guidance prior to bid submission. However, plans should note that such guidance provided in advance of the bid submission process is not a guarantee that CMS will approve the bid. As such, we believe this proposal, if implemented, would create efficiency while imposing relatively little burden on MA plans.

In addition, we proposed at § 422.102(f)(3)(iv) that MA plans will be required to document and submit to CMS upon request each determination that an enrollee is not eligible to receive an SSBCI. We believe that requiring an MA organization to support its SSBCI offerings with a written bibliography of relevant acceptable evidence and an MA plan to document denials of SSBCI work together to ensure that SSBCI are being implemented in an evidence-based, non-discriminatory, and fair manner. The evidence base established by an MA organization could serve to inform an MA plan's objective criteria for determining eligibility. By requiring an MA plan to document instances of SSBCI denials, we believe this proposal will improve the experience of MA plans, enrollees, and CMS in managing and oversight of appeals of such denials. Further, it will help ensure that MA plans are not denying access to SSBCI based on factors that are biased or discriminatory or unrelated to the basis on which the SSBCI are reasonably expected to improve or maintain the health or overall function of the chronically ill enrollees. For example, researchers have identified that certain algorithms that have been used to decide who gets access to additional services can have clear racial bias, when factors such as expected future cost or expected future utilization are incorporated into the algorithm.[86] By codifying CMS' authority to decline to approve a bid that includes an SSBCI not supported by evidence, this proposal also serves to ensure appropriate program administration and oversight.

Finally, we proposed to make a technical edit to § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. In our June 2020 final rule, we noted that section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who, among other requirements, ''[h]as a high risk of hospitalization or other adverse health outcomes[.]'' We then indicated that ''we propose to codify this definition of a chronically ill enrollee'' at § 422.102(f)(1)(i). However, our regulation at § 422.102(f)(1)(i)(A)*(2)* currently reads: ''Has a high risk of hospitalization of other adverse outcomes[.]'' We proposed to substitute ''or'' for the second ''of'' in this provision, such that it aligns with the statutory language that we intended to codify in our regulation.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Commenters were overall very supportive of our efforts to improve SSBCI offerings and ensure that these benefits provided value to enrollees. Commenters expressed support for our stated goals of ensuring that SSBCI were supported by evidence, and that MA rebate dollars were used to benefit enrollees.

Response: We appreciate the support of our proposal.

Comment: Some commenters expressed support for the degree of flexibility CMS proposed to include as part of its relevant acceptable evidence standard. However, several commenters sought clarification regarding aspects of our proposal. Specifically, several commenters sought clarification about whether CMS would request bibliographies as part of the bidding process, expressing concern that plans would have very little time to address any deficiencies.

Response: We appreciate commenter's support and reassert that we did not propose to require plans to submit their bibliographies with their bids. The provision proposed and finalized at § 422.102(f)(3)(iv) gives CMS the necessary flexibility to request to see

[86] *See, e.g.,* Ziad Obermeyer et al., Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 366, 447–453 (2019). DOI:10.1126/science.aax2342.

plans' bibliographies at any time during the bidding process or during the contract year; this may be helpful or even necessary to ensure compliance with the statutory and regulatory requirements for SSBCI. Our oversight of the MA program is enhanced by having access to bibliographies upon request and will lead to more effective and useful SSBCI offerings for Medicare beneficiaries. We will also provide time for plans to respond to any concerns CMS raises about SSBCI evidence bases during the bid process to allow plans to address any concerns expressed about submitted bibliographies and the associated benefits and make modifications to their bids as needed.

Comment: We received some comments which expressed opposition to our proposed SSBCI evidentiary standard, specifically the requirement that plans provide ''all relevant acceptable evidence.'' Commenters were largely in agreement that the proposed requirement would be too burdensome. Some commenters were concerned that the requirement would stifle innovation, especially for SSBCI benefits, which may not have a large evidence base. Some commenters felt that the standard should be limited to a certain minimum number of sources or to information from specific sources. Additionally, some commenters asked that CMS recognize a good faith effort in collecting ''all relevant acceptable evidence.'' They proposed that instead of ''all'' evidence, CMS accept a ''comprehensive'' or ''reasonable'' bibliography. A commenter suggested, to limit burden on plans, that CMS identify a singular research resource from which plans would be required to source published literature.

Response: We appreciate these comments, and we share this desire to foster continued innovation in benefits that are reasonably expected to maintain or improve the health or overall function of chronically ill enrollees. While we anticipate that plans have been identifying or developing evidence to support their SSBCI each year, toward ensuring compliance with the reasonable expectation standard and further ensuring that administering the SSBCI offerings makes business sense, we do not wish to have the unintended effect of limiting SSBCI offerings or stifling innovation. We recognize that for some benefits, which are more commonly offered or generally agreed upon to have a positive impact on the health of an individual, there may be a large number of studies, reports, and other sources of evidence available. Collecting and listing all such evidence produced within the last 10 years with assurances that no relevant citations were missed may be unrealistic.

To this end, we are modifying our proposed language at § 422.102 (f)(3)(ii) to require plans to include in their bibliographies ''a comprehensive list'' of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered. We proposed requiring plans to include ''all relevant acceptable evidence'' in these bibliographies. We intend that this change to the final rule will allow plans, especially those offered by smaller MA organizations or organizations with more limited resources, to meet the requirements without exhaustive efforts to find evidence from every available source. However, we note that plans must demonstrate genuine efforts to be thorough and inclusive of evidence related to the SSBCI offered. We also reiterate that plans must provide any available negative evidence and literature, which means including studies beyond those which present findings favorable to its SSBCI offering. Plans must demonstrate best efforts in including all evidence which adheres to the requirements proposed at § 422.102 (f)(3).

We are not limiting the sources from which plans may pull their evidence base as suggested by a commenter as we wish to provide flexibility for plans to cull from sources they deem acceptable to comply with the standards proposed. Additionally, we are not imposing a minimum number of bibliographic citations for a certain SSBCI. However, we expect that for more established items or services, plans are accordingly including a greater number of citations as there are likely to be a greater number of studies and investigations into the impact such items or services have on the studied sample group. Further, instituting such a minimum number of citations may be limiting for plans offering SSBCI which are less established and may not be able to meet such an arbitrary requirement. We note, however, that CMS may propose such a requirement in future rulemaking if it becomes evident that plans are not making a good faith effort in complying with the requirements or are allowing for SSBCI items or services with little to no evidence which do not meet the ''reasonable expectation'' standard.

While, as modified in this final rule, requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS may require plans to conduct further research than they currently do, we anticipate that the new burden will be manageable to the extent that the plans are building on existing efforts to ensure that their SSBCI offerings meet the ''reasonable expectation'' standard in the statute and currently at § 422.102(f)(1)(ii). As noted in the preamble, we expect that MA plans are already proactively conducting similar research and establishing written policies for implementing SSBCI based on this research when designing them. Additionally, MA plans may seek guidance from CMS regarding SSBCI items or services not defined in the PBP or in previous CMS guidance prior to bid submission. However, plans should note that such guidance provided in advance of the bid submission process is not a guarantee that CMS will approve the bid. To the extent that plans must conduct research anew to support novel, innovative SSBCI, we note that plans must only do so in the absence of large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, or large systematic reviews or meta-analyses summarizing the literature of the same (as proposed at § 422.102(f)(3)(i)), as well as any other evidence including case studies, federal policies or reports (as proposed at § 422.102(f)(3)(iii)).

Comment: Several commenters expressed concern about the timing of implementation for this proposal and requested that CMS delay implementation of proposed § 422.102(f)(3) until calendar year 2026, or until bidding for CY2026.

Response: While we appreciate that MA organizations may wish for additional time to collect evidence which adheres to the requirement, as noted in this preamble, plans should already have an evidence base to support their current benefit offerings. The reasonable expectation standard is not changing under this final rule and MA plans have been submitting bids for and offering SSBCI on the basis that the items and services are reasonably expected to improve or maintain the health or overall function of chronically ill enrollees for several years. Therefore, it is not necessary to delay implementation of the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS. We believe that plans should already have evidence to show their benefit offerings have a reasonable expectation of improving or maintaining the health or overall function of their chronically ill enrollees, and therefore collating information sufficient to comply with

our standard as proposed will not be an undue burden that warrants a delay in implementation. Therefore, we are finalizing these changes to § 422.102(f)(3) for coverage beginning on and after January 1, 2025, and will apply these standards in evaluating bids for 2025.

Comment: Several commenters expressed concerns that CMS' proposed standards for bibliographies are too strict, and that CMS should accept alternative research or studies beyond those explicitly mentioned. Some commenters expressed concern that the proposed standard would be particularly burdensome on MA Special Needs Plans (SNPs) that serve a wide variety of chronic conditions. Some commenters also identified certain types of services, such as home-based services, or services for certain enrollees, such as those receiving residential treatment, which they felt would be more challenging to fit into our proposed standard.

Response: Our proposed requirements were purposefully broad and flexible in what evidence would be acceptable to support a given SSBCI. As we are finalizing in this final rule, plans must first present a comprehensive list of literature published in a peer-reviewed journal, including large, randomized controlled trials or prospective cohort studies with clear results, systematic reviews, and meta-analyses—the evidence we described in proposed (and finalized) § 422.102(f)(3)(i). Per the finalized language at § 422.102(f)(3)(ii), the bibliography must include a comprehensive list of relevant acceptable evidence published within the 10 years prior to June preceding the start of the contract year, including any available negative evidence and literature. Requiring a broad scope of relevant acceptable evidence is necessary so that CMS may be apprised of both positive and negative research related to a specific item or service that an MA plan proposes to cover as an SSBCI. When studies are not available, an MA plan may include in its bibliography such items as case studies, Federal policies or reports, and internal analyses that investigate the impact that the item or service has on the health or overall function of its recipient—the evidence we described in proposed 42 CFR 422.102(f)(3)(iii). As proposed and finalized, paragraph (f)(3)(iii) does not require an MA plan to include evidence in these other types of case studies, federal policies or reports, internal analyses, or other investigation about the item or service that the MA plan proposes to cover as an SSBCI; the standard to provide a comprehensive list of relevant evidence is limited to the specific, more reliable materials described in paragraph (f)(3)(i). In the absence of studies described in paragraphs (f)(3)(i) and (ii), plans must include in their bibliographies the types of evidence described in § 422.102(f)(3)(iii), as proposed and finalized.

It is not necessary for CMS to be overly prescriptive in listing every type of acceptable evidence that a plan may collect and submit. As noted in this preamble, CMS does not wish to hamper innovation in offering new benefits. At the same time, we are concerned that any further broadening of this standard may make the requirement meaningless when keeping in mind that this proposal is meant to ensure quality care for chronically ill individuals. We will consider in future rulemaking whether it should refine this standard, including but not limited to being more prescriptive regarding the acceptable sources of evidence. For now, we believe it appropriate to promote flexibility in demonstrating that a given SSBCI offering complies with the reasonable expectation standard.

To that end, while we recognize that providing ''a comprehensive list of relevant acceptable evidence'' may sometimes mean a large number of studies are collected for a single benefit, gathering this evidence base is critical for greater review and scrutiny of these benefits in order for CMS to maintain good stewardship of Medicare dollars, and for ensuring that the SSBCI offered are consistent with applicable law and those most likely to improve or maintain the health or overall function of chronically ill enrollees. Requiring a broad scope of relevant acceptable evidence over a specified period of time is necessary so that CMS may be apprised of both positive and negative research related to a specific item or service that an MA plan proposes to cover as an SSBCI.

Additionally, we reassert that the relevant acceptable evidence need not necessarily relate to a specific chronic condition. We note there are some conditions for which there is little evidence relating to non-medical services which may benefit an individual. As we noted in this preamble, while ideally the evidence would include the specific chronic condition used by the MA plan in its SSBCI eligibility criteria and how the specific item or service would address that specific chronic condition, we are not making this a requirement at this time. We also note that relevant acceptable evidence does not necessarily have to be related to Medicare eligible populations. Acceptable studies or other sources of evidence may focus on other groups, including individuals in specific geographies or underserved communities. Since plans may consider social determinants of health (SDOH) as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI (42 CFR 422.102(f)(2)(iii)), we recognize that some relevant acceptable evidence may also be focused on certain communities that share a characteristic other than Medicare eligibility status. We therefore do not agree that specific types of MA plans, like SNPs, or services like residential treatment noted by the commenter would have difficulty meeting the requirement for the above reasoning.

Comment: Several commenters noted that some SSBCI services are generally accepted as regular supplemental benefits as well and recommended that such services be exempt from the requirement. Alternatively, some commenters suggested CMS make a list of specific items or services that may be offered as SSBCI and associated supporting bibliographies publicly available, such that plans could access them when choosing to provide those services. Many commenters recommended that CMS identify SSBCI that are supported by a robust evidence base and exempting those items or services from these requirements.

Response: While we agree there are some SSBCI which are offered by a large number of plans, and for which a large evidence base exists, we are not finalizing such a list at this time. Additionally, while we requested comment on specific items or services for which this requirement should not apply, commenters did not provide specific examples beyond a suggestion that CMS develop a ''core list'' of approved-and therefore exempt-SSBCI services. Therefore, we are finalizing this proposal that the MA plan develop a bibliography of specific types of evidence related to the proposed SSBCI without modification. CMS may consider developing and publishing a core list of SSBCI which are exempt from the requirement in future rulemaking should we determine that some services have a sufficiently robust evidence base. In addition, even for items and services that meet the standard of being primarily health related in § 422.100(c)(2), when an MA plan offers those benefits as SSBCI, the MA plan is necessarily limiting the coverage to specific chronically ill enrollees; it is appropriate to ensure that

the basis for that limitation is grounded in relevant acceptable evidence.

Comment: Some commenters suggested that, in the absence of any relevant acceptable evidence, CMS accept a rationale statement or allow plans to offer services for 1–2 years while the plan gathers internal data to support the continued offering of the benefit.

Response: While we reiterate our wish that MA plans continue to innovate and offer solutions to enrollees in the form of SSBCI, MA plans must use appropriate resources to test these benefits. Offering SSBCI where there is not a sufficient basis to conclude that the statutory and regulatory standards for such benefits under section 1852(a)(3)(D) of the Act and § 422.102(f) have been met is not appropriate. We decline to create an exception in our final rule for items and services which do not meet the ''relevant acceptable evidence'' criteria, a standard which CMS believes is sufficiently broad and flexible to accommodate less established SSBCI. Indeed, CMS proposed to allow plans to support SSBCI offerings through internal analyses in the absence of other established evidence. We note, however, that in addition to providing at least an internal analysis for an SSBCI for a current plan year, plans may leverage their experience in offering SSBCI to refine internal analyses for future plan years.

Comment: Some commenters were concerned that plans would not wish to devote the necessary resources to establish the bibliography at the time the bid is submitted and would instead pass this responsibility on to the businesses or organizations that provide the specific SSBCI benefits. These commenters expressed concern that these entities may not have the resources to do so or would be overburdened by the requirement. A few commenters requested clarification regarding the use of hyperlinks in the bibliography, including how to address internal analyses or when research is behind a ''paywall.''

Response: As with certain other programmatic requirements, MA plans may delegate functions to first tier, related, or downstream entities, subject to MA program rules such as § 422.504(i), and these requirements are no exception. MA plans are ultimately responsible for ensuring compliance with all federal law, including these new requirements, regardless of whether plans gather studies or conduct research directly or outsource those functions first tier, related or downstream entities. As it relates to our hyperlink requirement, plans must ensure that CMS can access completely each resource cited in the bibliography for an SSBCI. If the study is behind a ''paywall,'' is an internal analysis, or is otherwise not accessible through a hyperlink, the plan must provide such evidence directly to CMS upon request.

Comment: We received mixed comments regarding exclusion from the new requirements proposed and finalized in § 422.102(f)(3) (that is, the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS) of SSBCI that are reductions in cost-sharing for Parts A and/or B benefits, or reductions in cost sharing for other supplemental benefits which are not SSBCI. Some commenters were supportive of this exclusion while others felt that excluding cost-sharing benefits would mean plans offer fewer benefits which are not reductions in cost-sharing. Additionally, a commenter requested that CMS exclude from the requirement primarily-health related SSBCI that are substantially similar to mandatory supplemental benefits.

Response: We appreciate this feedback. At this time we are not extending the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS to apply as well to SSBCI that are reductions in cost-sharing, as we intend for this proposal to focus on the evidence base for SSBCI that are additional primarily health-related supplemental items and services and non-primarily health-related supplemental items and services, and not the level of cost borne by enrollees in accessing other covered benefits. We may consider in future rulemaking whether to subject SSBCI offered as cost sharing to these evidentiary requirements. However, we note that MA plans must still be able to explain how the SSBCI reduction in cost sharing meets the applicable statutory and regulatory standards, including the reasonable expectation standard.

We are also not exempting any particular SSBCI beyond those which are cost-sharing reductions. While some plans may choose to cover services which are substantially similar to already approved mandatory supplemental benefits, at this time, we are not making a distinction between services which are ''substantially'' similar to mandatory supplemental benefits, which vary by plan, and those which are not ''substantially'' similar.

Comment: We received several comments regarding our request for feedback on whether to codify a requirement that plans must follow their written policies for determining SSBCI eligibility. These comments were overwhelmingly supportive and additionally suggested that CMS require plans publish their written requirements for SSBCI eligibility on a public-facing website.

Response: We appreciate this feedback and support. We noted in this preamble that we anticipated plans were already following their written policies for determining SSBCI eligibility, policies which are a current regulatory requirement. We therefore believe amending the regulation to more clearly require compliance with the written policies is a logical next step and should not present a change in practice for plans. We are finalizing this aspect of the proposal without modification by finalizing the changes to redesignated paragraph (f)(4)(iii) as proposed.

We also appreciate the suggestion that plans publish their written SSBCI eligibility requirements, and while we are not finalizing such a requirement at this time, we may consider this in future rulemaking. We note that currently plans are expected to include SSBCI eligibility criteria in their Evidence of Coverage (EOC) and Annual Notice of Change (ANOC) documents. We stated in the June 2020 final rule ''[. . .]It is our expectation that plans communicate information on SSBCI to enrollees in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits.''

Comment: Some commenters supported our proposed change that plans must document SSBCI eligibility denials rather than approvals. Many commenters further suggested CMS require documentation of approvals as well as denials, rather than the CMS proposal to document only denials. A commenter also suggested CMS require additional data collection such as demographic information about the enrollee when a plan collects information for approval or denial of eligibility for an SSBCI benefit. Further, a commenter noted that by capturing both approvals and denials, CMS may be able to compare statistics of approvals and denials across plans.

Response: We appreciate this feedback and are finalizing paragraph (f)(4)(iv) (redesignated from existing paragraph (f)(3)(iv) with changes) with changes to require MA plans to document both approvals and denials of SSBCI eligibility. We agree that documenting both approvals and denials will give a more complete and comprehensive understanding of how plans are implementing coverage of SSBCI. In addition, this information

may assist us in evaluating how MA plans are marketing their benefits and exercising necessary oversight of their offerings. Since plans are already required to document approvals at current § 422.102(f)(3)(iv), we do not feel that this change should present a significant alteration of burden for plans from what we proposed in the November 2023 proposed rule.

We originally proposed documenting denials of SSBCI eligibility not only to increase ease of monitoring and oversight by CMS of whether benefits are being furnished consistent with how MA plans describe them but also to better position plans should enrollees appeal their SSBCI eligibility denials. However, commenters rightly pointed out that without the full picture of both approvals and denials, CMS may not be able to fully understand how plans are using their resources as it relates to SSBCI. If, for example, there are many denials as compared to approvals, it may alert the plan and CMS to an improper marketing of the benefit, or of overly broad recommendations of the benefit by a physician. Further, we agree with the commenter that by capturing both approvals and denials, CMS may be able to compare statistics of approvals and denials across MA plans, which, over time, may allow CMS to better determine if plans are improperly denying or approving SSBCI eligibility for plan enrollees. These additional capabilities and insights, which will be possible when there is adequate documentation of both approvals and denials, may allow for CMS to further refine SSBCI policy in future rulemaking to improve the enrollee experience and improve CMS's stewardship over Medicare dollars.

For these reasons, we are finalizing the proposal to require that MA plans document its eligibility determinations with a modification to require MA organizations to document both approvals and denials of eligibility for an enrollee to receive a particular SSBCI in § 422.102(f)(4)(iv).

Additionally, we are not requiring plans to report to CMS documentation regarding the approvals or denials on a regular basis at this time. However, CMS may request this data on a case by case or ad hoc basis or may incorporate this into regular reporting by MA organizations under §§ 422.504(f)(2) or 422.516(a). We also acknowledge concerns about equity and equitable treatment of enrollees, concerns which we share. It is our belief, through the modification of this proposal to include documentation of both approvals and denials, that MA plans will be additionally mindful of these concerns when making determinations. We note that plans may choose to include additional information, including demographic information about the enrollee, when documenting approvals and denials; however, CMS is not requiring plans to collect or submit this information as part of § 422.102(f). We may consider implementing such requirements in future rulemaking. We note that CMS has addressed some concerns regarding health equity and social risk factors elsewhere in this final rule. In the section titled ''Annual Health Equity Analysis of Utilization Management Policies and Procedures'' CMS sets forth additional requirements related to prior authorization determinations and their impact on health equity for MA organizations.

Comment: We solicited feedback on whether to exempt SSBCI from the general rule reflected in § 422.111(d) that MA plans may change certain plan rules during the year so long as notice is provided to enrollees. Some commenters urged that plans should not be allowed to change the eligibility requirements at all, while others suggested that the requirements should only be changed if eligibility were expanded to allow for more enrollees to benefit from services offered. A few commenters expressed concern about prohibiting changes in SSBCI eligibility policies during the coverage year as it may limit plan flexibility.

Response: We appreciate this feedback and the desire of commenters to preserve benefits available to enrollees and reduce confusion regarding plan requirements. This is a desire we share. We agree with commenters who expressed concern that changes during the coverage year to evidentiary standards or the objective criteria applied when determining eligibility for an SSBCI may disrupt or undermine a chronically ill enrollee's access to SSBCI. As commenters noted, changes in eligibility criteria and standards during the coverage year may be used to limit chronically ill enrollees' access to benefits. Most comments received on this topic urged us to exempt SSBCI from our general rule permitting changes in plan rules during the coverage year so long as notice is provided to enrollees. While some commenters suggested allowing changes only if such changes would expand access to the SSBCI, we believe that prohibiting changes to eligibility criteria and evidentiary standards for SSBCI altogether would minimize the potential for confusion and disagreement regarding whether a change does in fact expand access to a benefit. Moreover, this policy is consistent with another policy we are finalizing related to SSBCI eligibility disclaimers; ensuring that the disclaimers on marketing during the annual enrollment period are as accurate later in the coverage year as when beneficiaries are making enrollment decisions will improve the usefulness and applicability of the disclaimer. Taken together, these policies serve our goal of minimizing enrollee confusion regarding eligibility for certain SSBCI.

For these reasons, we are also adding new paragraph (f)(4)(v) as part of the changes we are finalizing to § 422.102(f) in this rule. New paragraph (f)(4)(v) requires that an MA plan offering SSBCI must maintain without modification for the full coverage year for the SSBCI offered, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations.

While CMS considered additionally prohibiting plans from making changes to their utilization management policies related to SSBCI during the coverage year, we are not finalizing such a prohibition at this time. It is important that plans have the flexibility to relax utilization management criteria and policies in the event of extraordinary circumstances. For example, during the COVID–19 public health emergency, CMS encouraged plans in the HPMS memo titled ''Information Related to Coronavirus Disease 2019—COVID–19'' to waive or relax prior authorization policies in order to facilitate enrollees' access to services with less burden on beneficiaries, plans and providers. We wish to allow plans continued flexibility to address such extraordinary circumstances, including disasters, declarations of state of emergency or public health emergencies, through changes made to utilization management policies as appropriate.

Comment: A commenter requested CMS not allow plans to change eligibility criteria for SSBCI during the plan year. However, the commenter requested that if CMS permitted plans to change eligibility criteria, or utilization management policies during the plan year, CMS should create a Special Enrollment Period (SEP) that allows enrollees to disenroll from the MA plan based on changes to plan rules.

Response: We appreciate this comment. We agree that changing eligibility criteria policies for SSBCI, benefits which may be heavily marketed to potential enrollees, could cause difficulties for chronically ill enrollees, especially if they relied on information about the availability of SSBCI benefits

in making a plan election. We do not wish these enrollees to come to rely on such services, only to be unable to access them during the plan year, or to be surprised by service denials or unexpected high service costs. In this final rule, CMS is prohibiting plans from making changes to eligibility requirements for SSBCI by requiring that plans offering SSBCI maintain without modification for the full coverage year, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations. Due to this change, an SEP is not necessary.

Comment: A commenter requested additional clarity about the bibliography review process, suggesting that CMS codify its process for reviewing bibliographies.

Response: While we appreciate the commenter's concerns regarding the timeline and review process CMS will use in reviewing the bibliographies prepared by MA organizations, we are not finalizing any formal process at this time. We believe that plans which offer SSBCI should already have strong evidence to support that such benefits will provide value to the enrollees by improving or maintaining the health or overall function of the enrollees. Therefore, we do not feel it is necessary to codify a formal review process which may be overly burdensome for plans, and overly restrictive on CMS. However, after initial years of implementation of this requirement, we may reevaluate this position about when and the extent to which CMS should request and review the bibliographies that this final rule requires. If there are indications that plans have not been responsibly offering benefits and generally adhering to requirements or if we determine that a more pro-active or formal approach to SSBCI review is necessary, we may consider future changes.

Comment: A commenter recommended CMS allow studies older than 10 years old, as they believed that some services would not be the subject of more current research such that there would be sufficient evidence to support the benefit.

Response: Under our proposal, MA plans are permitted to include studies published over 10 years ago in their bibliography. We are finalizing that MA plans are required to include a comprehensive list of studies constituting relevant acceptable evidence published within the past 10 years, including any available negative evidence and literature.

Comment: A commenter noted that the lack of clinical codes for these benefits made tracking outcomes difficult as enrollees may use different ''variations'' of a service, and it is difficult to prove that a specific SSBCI makes an impact without a reliable control group.

Response: We appreciate that measuring the impact of non-primarily health related benefits may be challenging in the absence of standard clinical codes. That said, our proposal does not require plans to prove that their specific SSBCI improved or maintained the health or overall function of the specific chronically ill enrollees who received the benefit. Instead, we are further implementing the existing statutory standard, under which an SSBCI must have a reasonable expectation of improving or maintaining the health or overall functioning of a chronically ill enrollee, and establishing requirements to ensure that the statutory requirements are met when SSBCI are included in MA bids. While evidence regarding the impact of a specific SSBCI on a specific sample of chronically ill enrollees might be valuable in demonstrating compliance with the reasonable expectation standard, this is not a requirement we are imposing as part of this final rule.

Comment: Some commenters recommended changes to the relevant acceptable evidence aspect of the proposal as it relates to SNPs. A commenter recommended that CMS change the policy for D–SNPs specifically. They recommend that, in instances where an SSBCI benefit overlaps with a Medicaid benefit, the plan should provide additional evidence to show that the benefit has a reasonable expectation of improving the health outcome of the D–SNP enrollees. Another commenter recommended that CMS require D–SNP plans to provide evidence that their SSBCI provides unique value to a substantial portion of their expected enrollee population eligible for SSBCI and will not be duplicative of other benefits they would already receive.

Response: We appreciate these comments. While we share the commenter's concern for D–SNP enrollees, specifically that these enrollees be able to access both Medicare and Medicaid benefits as necessary, we did not propose and are not adopting specific Medicare-Medicaid benefit coordination rules for SSBCI. The requirements we proposed and are finalizing in § 422.102(f)(3) are intended to ensure that there is relevant acceptable evidence on which to conclude that specific items and services that an MA plan intends to cover as SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We note that CMS already expects that D–SNPs use flexibility to design their benefits in a way that adds value for the enrollee by augmenting and/or bridging a gap between Medicare and Medicaid covered services and are therefore not modifying our requirements regarding SSBCI bibliographies to reflect any additional burden or requirement on D–SNPs specifically.

Comment: A commenter recommended CMS allow plans to include studies that focus on ''different sites of care'' or ''methods of implementation'' from those proposed for the plan benefit.

Response: Under our proposal, plans may cite studies that concern different sites of care or methods of implementation compared to how plans intend to implement their specific SSBCI. While ideally, relevant acceptable evidence will include studies that align with how plans will implement their SSBCI, and to whom the plans target their SSBCI, we recognize that most relevant studies will vary in the exact benefit and population studied. We believe studies that consider a benefit design and implementation similar to but not precisely the same as that proposed by the plan is still relevant for demonstrating compliance with our reasonable expectation standard.

After consideration of the comments, and for the reasons provided in our November 2023 proposed rule, we are finalizing our proposed revisions to § 422.102(f) with three modifications. First, we are finalizing our proposals to redesignate current paragraph § 422.102(f)(3) to § 422.102(f)(4). We are finalizing at § 422.102(f)(3) our proposed policy requiring the MA organization to be able to demonstrate through relevant acceptable evidence that the item or service to be offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee and must, by the date on which it submits its bid to CMS, establish a bibliography of ''relevant acceptable evidence'' concerning the impact that the item or service has on the health or overall function of its recipient.

We are further finalizing our proposal, at paragraph (f)(3)(i) that relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to

investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

We are modifying our proposal at § 422.102(f)(3)(ii) that an MA organization must include in its bibliography ''all relevant acceptable evidence'' published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered. Instead, in response to comments received, we are finalizing that an MA organization must include in its bibliography ''a comprehensive list of relevant acceptable evidence [. . .] including any available negative evidence and literature.''

We are finalizing at § 422.102(f)(3)(iii) that, if no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, Federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

Second, we are also finalizing our proposal to explicitly require at § 422.102(f)(4)(iii) that MA plans must apply their written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI. We are effectuating this policy by adding ''and apply'' to redesignated paragraph (f)(4)(iii)(A) as we proposed. Further, based on comments received, we are finalizing an exemption to the general rule reflected at § 422.111(d) that MA plans may change plan rules for SSBCI during the coverage year. Specifically, we are finalizing at new § 422.102(f)(3)(v) that an MA plan offering SSBCI must maintain without modification for the full coverage year evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations.

Third, after considering comments received, we are modifying our proposal that MA plans would need to document denials of SSBCI eligibility instead of approvals. Instead, we are adopting a requirement that MA plans must document both approvals and denials of SSBCI eligibility. Specifically, we are modifying proposed § 422.102(f)((4)(iv) to say ''Document each SSBCI eligibility determination, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.''

Fourth, we are finalizing our proposal without modification to add § 422.102(f)(5) to codify CMS's authority to decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. We are additionally finalizing our proposal that CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service. We are further finalizing our clarification that this provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and subpart F of this part nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

Finally, we are finalizing our technical edit proposed at § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. Specifically, we are substituting ''or'' for the second ''of'' in § 422.102(f)(1)(i)(A)(*2*), such that it reads ''Has a high risk of hospitalization or other adverse health outcomes.''

D. Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42))

Per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). When submitting an annual bid to participate in the MA program, an MA organization includes a Plan Benefit Package (PBP) (OMB 0938–0763) and Bid Pricing Tool (BPT) (OMB 0938–0944) for each of its plans where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS's annual PBP reviews as well as external reports. The 2023 Medicare Trustees Report showed that in the last decade, MA rebates quintupled from $12 billion in 2014 to $67 billion estimated for 2024, resulting in a total of over $337 billion going towards MA rebates over that time period. This increase, which was due to both the increase in MA enrollment and per MA beneficiary rebate growth, which included 27%–30% jumps each year from 2019 to 2023.[87] At the same time, CMS has received reports that MA organizations have observed low utilization of these benefits by their enrollees, and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees, which could be an important part of a plan's overall care coordination efforts.

CMS remains concerned that utilization of these benefits is low and has taken multiple steps to obtain more complete data in this area. For example, in the May 2022 final rule, we finalized expanded Medical Loss Ratio (MLR) reporting requirements, requiring MA organizations to report expenditures on popular supplemental benefit categories such as dental, vision, hearing, transportation, and the fitness benefit (87 FR 27704, 27826–28).[88] In addition, in March 2023, as a part of our Part C reporting requirements, we announced our intent to collect data to better understand the utilization of supplemental benefits, which was finalized, and beginning CY2024 requires MA plans to report utilization and cost data for all supplemental benefit offerings.[89] This data is collected in the information collection request Part C Medicare Advantage Reporting OMB 0938–1054.[90] Currently, there is no specific requirement for MA organizations, beyond more general care coordination requirements, to conduct outreach to enrollees to encourage utilization of supplemental benefits.

CMS understands that projected supplemental benefit utilization, that is, the extent to which an MA organization expects a particular supplemental benefit to be accessed during a plan year, is estimated by an MA organization in part by the type and extent of outreach conducted for the benefit.[91] [92] We are concerned that

[87] *https://www.cms.gov/oact/tr/2023.*

[88] Available at *https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and.*

[89] Available at: *https://www.cms.gov/medicare/enrollment-renewal/health-plans/part-c* and *https://www.cms.gov/files/document/cy2024-part-c-technical-specifications-01092024.pdf.*

[90] *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10261.*

[91] U.S. Government Accountability Office (GAO). ''MEDICARE ADVANTAGE Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.'' Report to Congressional

Continued

beneficiaries may make enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP) only to not fully utilize, or utilize at all, those supplemental benefits during the plan year. This underutilization may be due to a lack of effort by the plan to help the beneficiary access the benefits or a lack of easy ability to know what benefits have not been accessed and are still available to the enrollee throughout the year. Such underutilization of supplemental benefits may nullify any potential health value offered by these extra benefits.

Additionally, section 1854(b)(1)(C) of the Act requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that MA rebates are provided to enrollees in a way that they can benefit from the value of these rebate dollars. For example, analysis indicates that while supplemental dental benefits are one of the most widely offered supplemental benefits in MA plans, enrollees in these plans are no more likely to access these services than Traditional Medicare enrollees.[93]

As discussed, MA organizations are given the choice of how to provide MA rebates to their enrollees. Organizations may, instead of offering supplemental benefits in the form of covering additional items and services, use rebate dollars to further reduce Part B and Part D premiums, reduce cost sharing for basic benefits compared to cost sharing in Traditional Medicare, and reduce cost sharing in other ways, such as reducing maximum out-of-pocket (MOOP) amounts.

Over the last several years, CMS has observed an increase in (1) the number and variety of supplemental benefits offered by MA plans, (2) plan marketing activities by MA organizations, and (3) overall MA enrollment; we presume that an enrollee's plan choice is influenced, at least in part, by the supplemental benefits an MA plan offers because the absence or presence of a particular supplemental benefit represents a distinguishable and easily understood difference between one plan and another. We are also concerned that some MA plans may be using these supplemental benefits primarily as a marketing tool to steer enrollment towards their plan and are not taking steps to ensure that their enrollees are using the benefits being offered or tracking if these benefits are improving health or quality of care outcomes or addressing social determinants of health. We believe targeted communications specific to the utilization of supplemental benefits may further ensure that covered benefits (including those that are heavily marketed) are accessed and used by plan enrollees during the plan year. This outreach, in conjunction with the improved collection of utilization data for these supplemental benefits through MLR and through Part C reporting requirements, should help inform whether future rulemaking is warranted.

Finally, CMS is also 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. Several studies have pointed to disparities in health care utilization. For example, a Kaiser Family Foundation (KFF) study [94] found that there are significant racial and ethnic disparities in utilization of care among individuals with health insurance. Additionally, underserved populations tend to have a disproportionate prevalence of unmet social determinants of health needs, which can adversely affect health. We believe that the ability to offer supplemental benefits provides MA plans the unique opportunity to use Medicare Trust Fund dollars (in the form of MA rebates) to fill in coverage gaps in Traditional Medicare, by offering additional health care benefits or SSBCI that address unmet social determinants of health needs, and as such, all eligible MA enrollees should benefit from these offerings. Targeted outreach to enrollees that is specific to the utilization of supplemental benefits may also serve to further ensure more equitable utilization of these benefits.

The establishment of a minimum requirement for targeted outreach to enrollees with respect to supplemental benefits that have not been accessed by enrollees would standardize a process to ensure all enrollees served under MA are aware of and utilizing, as appropriate, the supplemental benefits available to them. Section 1852(c)(1) of the Act requires, in part, that MA organizations disclose detailed descriptions of plan provisions, including supplemental benefits, in a clear, accurate, and standardized form to each enrollee of a plan at the time of enrollment and at least annually thereafter. We proposed to use our authority to establish standards under Part C in section 1856(b)(1) of the Act to ensure adequate notice is provided to enrollees regarding supplemental benefits coverage. This proposal will further implement the disclosure requirement in section 1852(c)(1)(F) of the Act. Specifically, we proposed that MA organizations must provide a model notification to enrollees of supplemental benefits they have not yet accessed. We proposed to implement this by adding new provisions at §§ 422.111(l) and 422.2267(e)(42) to establish this new disclosure requirement and the details of the required notice, respectively.

This proposed requirement will ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plan that the enrollee has not yet accessed. We proposed that, beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the plan year, to each enrollee with information pertaining to each supplemental benefit available during that plan year that the enrollee has not begun to use. We understand that there may be a lag between the time when a benefit is accessed and when a claim is processed, so we would require that the information used to identify recipients of this notice be as up to date as possible at the time of mailing. MA organizations are not required to include supplemental benefits that have been accessed, but are not yet exhausted, in this proposed mid-year notice.

Understanding that not all Medicare beneficiaries enroll in an MA plan during the AEP, we specifically sought comment on how CMS should address the timing of the notice for beneficiaries that have an enrollment effective date after January 1. One possible approach we described as under consideration was requiring the notice to be sent six months after the effective date of the enrollment for the first year of enrollment, and then for subsequent years, revert to mailing the notice between the proposed delivery dates of June 30 and July 31. Another option was to not require the notice to be mailed for

Committee, 31 Jan. 2023, p. 20, *www.gao.gov/products/gao-23-105527.*

[92] U.S. Government Accountability Office (GAO). ''MEDICARE ADVANTAGE Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.'' Report to Congressional Committee, 31 Jan. 2023, p. 20, *www.gao.gov/products/gao-23-105527.*

[93] *https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/data-briefs/dental-coverage-status-and-utilization-preventive-dental-services-medicare-beneficiaries-poster.*

[94] *https://www.kff.org/report-section/racial-and-ethnic-disparities-in-access-to-and-utilization-of-care-among-insured-adults-issue-brief/.*

the first year of enrollment for those beneficiaries with an effective date of May 1 or later, as they would be receiving their Evidence of Coverage (EOC) around this same timeframe but may not have had sufficient time to access these benefits. Those enrollees who would be exempt from the mailing, based on their enrollment effective date, would then receive the notice (if applicable because one or more supplemental benefits have not been accessed by the enrollee) between June 30 and July 31 in subsequent enrollment years.

For each covered mandatory supplemental benefit and optional supplemental benefit (if the enrollee has elected) for which enrollee is eligible, but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in EOC. For SSBCI, MA organizations must include an explanation of the SSBCI covered under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must also provide point-of-contact information for eligibility assessment (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to address any other questions the enrollee may have about the availability of SSBCI under their plan. When an enrollee has been determined by the plan to be eligible for one or more specific SSBCI benefit but has not accessed the SSBCI benefit by June 30 of the plan year, the notice must also include a description of the SSBCI benefit to which the enrollee is entitled and must describe any limitations on the benefit. In the proposed rule, we noted the proposal to amend § 422.2267(e)(34) (discussed in section VI.B of this final rule), if finalized, would require specific SSBCI disclaimers for marketing and communications materials that discuss the limitations of the SSBCI benefit being offered; we also proposed that this mid-year notice must include the SSBCI disclaimer to ensure that the necessary information provided in the disclaimer is also provided to the enrollee in the notice.

Furthermore, we proposed that each notice must include the scope of the supplemental benefit(s), applicable cost sharing, instructions on how to access the benefit(s), applicable information on the use of network providers for each available benefit, list the benefits consistent with the format of the EOC, and a toll-free customer service number including, as required, a corresponding TTY number, to call if additional help is needed. We solicited public comment on the required content of the mid-year notice.

We also requested public comment on our proposal to require MA plans to provide enrollees with mid-year notification of covered mandatory and optional supplemental benefits (if elected) that have not been at least partially accessed by that enrollee, particularly the appropriate timing (if any) of the notice for MA enrollees who enroll in the plan mid-year. A discussion of these comments, along with our responses follows.

Comment: Some supporters of this provision expressed a belief that the Mid-Year Notice is not strong enough to support the needs of enrollees or should be amended for other reasons. A commenter suggested that an annual cycle was insufficient, and that the notice should be mailed monthly. Several commenters suggested the notice be sent quarterly. A commenter suggested the notice be sent three months after enrollment for anyone with an effective date before September 1st, and for the enrollee to receive it during the annually established timeframe in subsequent years. A commenter suggested the notice be sent after the first quarter of the plan year. Another commenter suggested that the notice should be mailed soon after an enrollee's coverage is effectuated, regardless of whether the effectuation date is January 1st or after, and should include all supplemental benefits available under the plan. Another commenter stated that partially utilized benefits should be included in the notice.

Response: We thank these commenters for their support and attention to detail. We are finalizing § 422.111(l) (requiring the Mid-year Notice to be sent and the timing) and § 422.2267(e)(42) (the content requirements for the Mid-Year Notice) as proposed. The purpose of the notice is to inform those enrolled in an MA plan about supplemental benefits that have not been accessed, rather than to inform them of all available supplemental benefits. We believe the EOC is the appropriate communication for informing beneficiaries of all supplemental benefits offered under a particular plan. We also note that it is important to give beneficiaries ample time to access the benefits before providing notice of unused supplemental benefits. We believe the timeframes set forth in this rule provide sufficient time. In addition, monthly or quarterly reminders may be burdensome or lose their effectiveness in providing a reminder to enrollees about the benefits available to them. However, after assessing the efficacy of this provision over time, we may make amendments to the Mid-Year Notice and its requirements in future rulemaking.

Comment: We received many comments that expressed concern about burden and complexity, specifically regarding the proposed annual deadline (July 31) and cost of providing personalized information to each enrollee. With respect to the annual deadline a commenter asked CMS to extend the deadline to August 15, and another believed they would need up to 8 weeks following June 30 to complete the process of printing and mailing. For various reasons, some commenters believed CMS underestimated the costs associated with printing and mailing documents that consist of personalized information; for example, a commenter stated their printing costs were always higher for personalized materials; some commenters estimated average document lengths would be much higher than the CMS estimate, from 18 to over 20 pages.

Response: The Mid-Year Notice of Unused Supplemental Benefits is intended to be a concise and user-friendly document, and we are committed to the formulation of a model design that is both informative and succinct. The length of the document will ultimately vary from enrollee to enrollee, depending on the number of supplemental benefits offered under the plan, the number and scope of supplemental benefits each enrollee may be eligible to receive, and individual utilization. As proposed and finalized, the notice must only include information about supplemental benefits that the enrollee has not yet begun to use by June 30.

Further, MA organizations have their own unique processes in place for compiling, printing, and disseminating information, and this may lead to variations in cost. Stakeholders will have further opportunity to comment directly on the model notice during the Paperwork Reduction Act process. We also believe that the notice will create an incentive for MA organizations to improve their education and outreach efforts regarding supplemental benefit access and utilization through their marketing and communication materials, during the enrollment process, and into the plan year. We believe that as supplemental benefits are better understood and utilized by enrollees in the first half of the year, the shorter the Mid-Year Notice will become.

Further, the requirement to notify enrollees about their unused supplemental benefits can provide MA organizations with the opportunity to glean useful information to further tailor their PBPs. CMS believes MA organizations could gain valuable insights into their enrollees' healthcare needs and preferences based on the data needed to send these individualized notifications, if MA organizations choose to analyze this data. This notice can benefit MA organizations by encouraging them to thoughtfully reassess which supplemental benefits they choose to offer so they can steer away from unpopular types of supplemental benefits in the future, leading to a more impactful use of resources, including Medicare dollars.

Comment: Some commenters stated that our proposal lacks scope. A commenter believed that CMS should have defined ''supplemental benefits'' for the purpose of determining inclusion in the Notice. Another commenter stated the requirements of SSBCI and information needed were not clear. Another commenter asked CMS to clarify whether quarterly allowance benefits should be included in the Notice.

Response: To clarify, supplemental benefits include reductions in cost sharing and additional items and services that are not covered under Medicare Parts A, B and D. Per § 422.100(c), supplemental benefits must meet specific requirements in addition to not being covered by Medicare Parts A, B or D. The terms ''mandatory supplemental benefits'' and ''optional supplemental benefits'' are defined in § 422. SSBCI are supplemental benefits that are offered only to eligible enrollees with chronic conditions and are defined at § 422.102(f). Certain limitations on how and when MA plans may offer supplemental benefits are addressed in §§ 422.100(c) and 422.102 that we do not summarize in depth here.

For purposes of the Mid-Year Notice requirement, all unused supplemental benefits that are offered by the MA plan must appear in the Mid-Year Notice regardless of whether the benefits are categorized on the PBP as mandatory, optional, or SSBCI. The only supplemental benefit that does not need to be included in the notice is cost-sharing reduction, and this change has been reflected in the final regulation text for clarification.

The regulation we proposed and are finalizing at § 422.2267(e)(42) lists the information that is required about the unused supplemental benefits. For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage. For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

For SSBCI, the Mid-Year Notice must include the SSBCI disclaimer specified at § 422.2267(e)(34) and additional information about the SSBCI. When an enrollee has not been deemed eligible, MA organizations must include an explanation of the SSBCI covered under the plan consistent with the format of other unused supplemental benefits, eligibility criteria for the SSBCI, and point-of-contact information for eligibility assessments, such as a customer service line or a separate dedicated line, to reach trained staff that can answer questions and initiate the SSBCI eligibility determination process. When an enrollee has been determined by the plan to be eligible for one or more specific SSBCI—but has not accessed the SSBCI benefit by June 30 of the plan year—the Mid-Year Notice for that enrollee must also include a description of the SSBCI to which the enrollee is entitled and must describe any limitations on the benefit, consistent with the format of other unused supplemental benefits.

In addition, as specified in § 422.2267(e)(42)(ii)(D), the Mid-Year Notice must include the following about each unused supplemental benefit listed in the Notice to each enrollee:

(*1*) Scope of benefit.

(*2*) Applicable cost-sharing.

(*3*) Instructions on how to access the benefit.

(*4*) Any applicable network information.

(E) Supplemental benefits listed consistent with the format of the EOC.

(F) A customer service number, and required TTY number, to call for additional help.

We believe that the regulation is sufficiently clear as to the scope and required content of the notice.

Comment: Some commenters believed CMS could meet the stated goal of increasing supplemental benefit utilization through non-regulatory means by encouraging MA organizations to use their existing resources to promote supplemental benefit usage. Examples included the incorporation of supplemental-benefit-focused abstracts into MA organizations' newsletters, reminders to enrollees to read their EOCs, and the addition of articles and reminders on plan websites.

Response: We encourage MA organizations to use other outlets available to them to inform enrollees of their supplemental benefits. This Notice provision represents a required minimum effort on the part of each MA organization and should not be understood to preclude other forms of outreach.

Comment: Several commenters believed there is much potential for enrollees to become confused, frustrated, and ultimately dissatisfied with their plans because they are ineligible to use a particular benefit. An example provided was meal delivery being available only post-surgery.

Response: As discussed in the proposal, MA organizations are required to provide descriptions of supplemental benefits clearly and accurately. Here, MA organizations must describe the scope of and include instructions on how to access each listed supplemental benefit, similar to how these benefits are described in the EOC. If the benefit is only made available under limited circumstances, this must be evident in the Mid-Year Notice. Moreover, we feel strongly that the risk of confusion or frustration is far outweighed by the benefits of informing enrollees of supplemental benefits that can be useful to improving or maintaining their health.

Comment: Some commenters suggested CMS adopt a non-personalized format that summarizes all supplemental benefits available under a plan regardless of whether the enrollee has used them. Reasons for this suggestion commonly included burden reduction for MA organizations and decreased likelihood of confusion for enrollees.

Response: We believe that a non-personalized summary of all supplemental benefits available under a plan could confuse enrollees and add unnecessary length to the Mid-Year Notice. Further, as discussed above, the purpose of the notice is to inform those enrolled in an MA plan about supplemental benefits that they have not accessed, rather than to inform them of all supplemental benefits available. Providing information on supplemental benefits that the enrollee has not used will focus the enrollee on the items and services that are covered by the plan that the enrollee has not accessed, but may still have time to access, during the remainder of the year. We believe the EOC is the appropriate communication for informing beneficiaries of all supplemental benefits offered under a particular plan.

Comment: Many commenters believed this provision will drive an uptick in

the utilization of supplemental benefits. A commenter expressed concern that the Mid-Year Notice may impact expected utilization in uncertain ways, threatening the integrity of what MA organizations project in their bids. Another commenter stated that MA organizations generally have an expectation that not all enrollees will use every benefit, including supplemental benefits. This commenter expressed concern that promoting use of supplemental benefits could result in unanticipated expenses for an MA organization and result in higher premiums.

Response: We believe that the Mid-Year Notice will generate an increase in the use of supplemental benefits. However, MA organizations should not presume enrollees are overutilizing or will over utilize benefits as we believe most enrollees will use their benefits only when they need them. We expect organizations to establish reasonable safeguards that ensure enrollees are appropriately directed to care.[95] Further, MA organizations regularly make determinations to manage utilization as is the case with SSBCI where they must have written policies for determining enrollee eligibility and must document its determination whether an enrollee is chronically ill (42 CFR 422.102). Section IV.C. of this final rule includes discussion of new SSBCI rules that could help to mitigate unnecessary utilization.

Comment: Some commenters stated the proposal does not strike an appropriate balance between administrative burden and enrollee impact—that the proposal adds confusion, complexity, and cost without any clear value or benefit; further, some believed the proposal is based on assumptions rather than data. For example, a commenter stated that the proposal indicates that utilization of supplemental benefits is low but does not specify the basis for that position. The commenter requested that CMS provide further evidence and explanation to support the claim that there is low supplemental benefit utilization, and that the cause is lack of enrollee awareness of benefits as opposed to the enrollee not needing or wanting to use the benefit. In addition, the commenter asked that CMS demonstrate that a Mid-Year Notice is the most suitable means to address low supplemental benefit utilization under the rulemaking framework of the Administrative Procedure Act.

Response: In the proposed rule, we did not claim that the only cause of low supplemental benefit utilization was lack of enrollee awareness of benefits as the commenter suggested. Rather, we noted that it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees, including as part of a plan's efforts in care coordination or otherwise. In addition, while we cited reports of low supplemental benefit utilization, we also noted that more complete data is needed in this area and provided examples of how CMS has taken multiple steps to obtain such data through both MLR and Part C reporting requirements. We stated that we will use findings obtained from this outreach requirement, in conjunction with the improved collection of supplemental benefit utilization data, to inform whether additional *future* rulemaking is warranted. Identifying and addressing potential underutilization of benefits funded in large part by the government through MA rebates is appropriate for us to ensure appropriate use of Medicare Trust Fund dollars. Further, to the extent that underutilization of supplemental benefits is not an issue and these benefits are widely accessed by enrollees, the number of Mid-Year Notices would decrease as proposed and finalized, our rule only requires a notice to individual enrollees about supplemental benefits that enrollees have not accessed.

As discussed in the proposal, the recent significant increase in the number and variety of supplemental benefit offerings combined with marketing activities and an increase in overall MA enrollment has led CMS to believe that an enrollee's plan choice is influenced, at least in part, by the supplemental benefits an MA plan offers. One purpose of the Mid-Year Notice is to address concerns that some MA plans may be using supplemental benefits primarily as marketing tools to steer enrollment; our policy as described here will help to ensure that covered benefits are accessed and used by plan enrollees during the plan year by ensuring that enrollees are aware about supplemental benefits that they have not yet used by June 30 of the applicable year. Any potential underutilization of benefits could be due to a lack of effort by the plan to help the beneficiary access the benefits, or a lack of easy ability to know what benefits have not been accessed and are still available to the enrollee throughout the year. This new notice is intended to address both.

Another purpose of the Mid-Year Notice is to address disparities in health care utilization, aligning with our goal to advance health equity in the MA program and pursue a comprehensive approach to advancing health equity for all by encouraging more equitable utilization of these benefits.

Finally, the Mid-Year Notice will further ensure that MA organizations fulfill their obligation to adequately disclose details and notice of supplemental benefit coverage.

Comment: Some commenters expressed concern about the ability to offer ''real-time'' information on the Mid-Year Notice. For example, one commenter mentioned that MA organizations use a wide variety of providers to furnish supplemental benefits, and that these providers have varying degrees of capability; some are community-based organizations with limited resources, and such providers may not be able to transmit utilization and claim information with the speed of more conventional provider types.

Response: We understand that supplemental benefits are often available through community-based providers that often do not have the budget for sophisticated software systems that transmit information in ''real-time.'' With respect to timeliness, we consider information that is up to date as of June 30 of the plan year to satisfy the requirement for accuracy.

Comment: Many commenters were satisfied with a provision start date of January 2026, but some asked for an extension to January 2027.

Response: We believe a start date of January 2026 gives MA organizations sufficient time to plan and implement processes for the Mid-Year Notice. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing §§ 422.111(l) as proposed and 422.2267(e)(42) with a modification to clarify that supplemental benefits in the form of cost-sharing reductions are excluded from the notice.

E. Annual Health Equity Analysis of Utilization Management Policies and Procedures

In recent years, CMS has received feedback from interested parties, including people with Medicare, patient groups, consumer advocates, and providers that utilization management (UM) practices in Medicare Advantage (MA), especially the use of prior authorization, can sometimes create a barrier for patients in accessing medically necessary care. Further, some research has indicated that the use of

[95] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms%2520memo%2520primarily%2520health%2520related%25204-27-18_194.pdf.*

prior authorization may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality,[96] due to several factors, including; the administrative burden associated with processing prior authorization requests (for example, providers and administrative staff serving historically underserved populations, in particular, may not have the time or resources to complete the prior authorization process, including navigating the appeals process [97]), a reduction in medication adherence, and overall worse medical outcomes due to delayed or denied care. Research has also shown that dual eligibility for Medicare and Medicaid is one of the most influential predictors of poor health outcomes, and that disability is also an important risk factor linked to health outcomes.[98]

On January 20, 2021, President Biden issued Executive Order 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (E.O. 13985).[99] 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. Consistent with this Executive Order, CMS announced ''Advance Equity'' as the first pillar of its 2022 Strategic Plan.[100] This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health care 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.'' [101]

The April 2023 final rule [102] included several policy changes to advance health equity, as well as changes to address concerns from interested parties about the use of utilization management policies and procedures, including prior authorization, by MA plans. CMS understands that utilization management is an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. The April 2023 final rule adopted several important guardrails to ensure that utilization management policies and procedures are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to covered items and services for people enrolled in MA plans. CMS also continues to work to identify regulatory actions that can help support CMS's goal to advance health equity and improve access to covered benefits for enrollees.

Authority for MA organizations to use utilization management policies and procedures regarding 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 statutory provisions. In addition, the MA statute and MA contracts cover both the basic and supplemental benefits covered under MA plans, so additional contract terms added by CMS pursuant to section 1857(e)(1) of the Act may also address supplemental benefits. Additionally, per section 1852(b) of the Act and § 422.100(f)(2), plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. These requirements apply to both basic and supplemental benefits. We consider utilization management policies and procedures to be part of the plan benefit design, and therefore they cannot be used to discriminate or direct enrollees away from certain types of services.

In the April 2023 final rule, CMS finalized a new regulation at § 422.137, which requires all MA organizations that use UM policies and procedures to establish a Utilization Management Committee to review and approve all UM policies and procedures at least annually and ensure consistency with Traditional Medicare's national and local coverage decisions and relevant Medicare statutes and regulations. Per § 422.137, 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. While this requirement will ensure that all UM policies and procedures are kept up to date, we believe that reviewing and analyzing these policies from a health equity perspective is an important beneficiary protection. In addition, such an analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization. For these reasons, we proposed to add health equity-related requirements to § 422.137. First, we proposed at § 422.137(c)(5) to require that beginning January 1, 2025, the UM committee must include at least one member with expertise in health equity. We proposed that health equity expertise includes, but is not limited to, educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity. Since there is no universally accepted definition of expertise in health equity, we referred to materials from the Council on Linkages Between Academia and Public Health Practice [103] and the National Board of Public Health Examiners,[104] to describe ''expertise in health equity'' in the context of MA and prior authorization.

We also proposed to add a requirement at § 422.137(d)(6) that the UM committee must conduct an annual health equity analysis of the use of prior authorization. We proposed that the member of the UM committee, who has health equity expertise, as required at proposed § 422.137(c)(5), must approve the final report of the analysis before it is posted on the plan's publicly available website. The proposed analysis will examine the impact of prior authorization at the plan level, on

[96] *https://www.hmpgloballearningnetwork.com/site/frmc/commentary/addressing-health-inequities-prior-authorization;* and *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/*

[97] *http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf,*

[98] *https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031*

[99] *https://www.federalregister.gov/d/2022-26956/p-227.*

[100] *https://www.federalregister.gov/d/2022-26956/p-228.*

[101] *https://www.cms.gov/pillar/health-equity.*

[102] ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120).

[103] *https://www.phf.org/resourcestools/Documents/Core_Competencies_for_Public_Health_Professionals_2021October.pdf*

[104] *https://www.nbphe.org/cph-content-outline/*

enrollees with one or more of the following social risk factors (SRF): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS chose these SRFs because they mirror the SRFs that will be used to measure the Heath Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and we believe it is important to align expectations and metrics across the program. Moreover, CMS is requiring this analysis to take place at the MA plan level because the relevant information regarding enrollees with the specified SRFs is available at the plan level, and we believe this level of analysis is important to discern the actual impact of the use of utilization management on enrollees that may be particularly subject to health disparities.

To gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs, the analysis, as proposed, must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Doing so, allows the MA plan and CMS to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs. We proposed that the analysis must use the following metrics, calculated for enrollees with the specified SRFS, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

Next, we proposed to add at § 422.137(d)(7) that by July 1, 2025, and annually thereafter, the health equity analysis be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website. We proposed that the health equity analysis must be easily accessible to the general public, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); in a machine-readable format with the data contained within that file being digitally searchable and downloadable from a link in the footer of the plan's publicly available website, and include a .txt file in the root directory of the website domain that includes a direct link to the machine-readable file, in a format described by CMS (which CMS will provide in guidance), to establish and maintain automated access. We believe that by making this information more easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans.

Finally, we welcomed comment on the proposal and sought comment on the following:

- Additional populations CMS should consider including in the health equity analysis, including but not limited to: Members of racial and ethnic communities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.
- If there should be further definition for what constitutes ''expertise in health equity,'' and if so, what other qualifications to include in a definition of ''expertise in health equity.''
- The proposed requirements for publicly posting the results on the plan's website under § 422.137(d)(7) to ensure the data will be easily accessible to both the public and researchers.
- Alternatives to the July 1, 2025, deadline for the initial analysis to be posted to the plan's publicly available website.
- Whether to add an additional requirement that the UM committee submit to CMS the link to the analysis report. This would allow CMS to post every link in one centralized location, which would increase accessibility and transparency.

In addition, we requested comment on any specific items or services, or groups of items or services, subject to prior authorization that CMS should consider also disaggregating in the analysis to consider for future rulemaking. If further disaggregation of a group of items or services is requested, CMS solicited comment on what specific items or services would be included within the group. For example, if CMS should consider disaggregating a group of items or services related to behavioral health treatment in the health equity analysis, what items or services should CMS consider a part of behavioral health treatment.

We invited public comment on this proposal and received over 140 comments. A summary of the comments received, and CMS's responses are below.

Comment: Nearly all commenters supported the proposal to add a member to the utilization management committee with expertise in health equity. A majority of commenters also supported the proposed definition of expertise in health equity. Commenters expressed gratitude for CMS's recognition that there is not currently a widely accepted definition of what qualifies as ''expertise in health equity,'' and that the proposed non-exhaustive list provides adequate flexibility and acknowledges the varied experiences and qualifications that could comprise health equity expertise.

Response: CMS appreciates the suggestions and support for this proposal. As outlined in the November 2023 rule, we do not believe there is a universally accepted definition of expertise in health equity. Therefore, CMS believes there is value at this stage in providing a non-exhaustive list of examples of what constitutes such expertise to avoid inadvertently excluding qualified individuals by being overly restrictive. The proposed and finalized regulation text lists examples to illustrate what constitutes expertise in health equity includes to guide MA organizations in identifying individuals with the necessary expertise and experience to fulfill this new role on the UM committee. We are finalizing that list without the phrase ''but is not

limited to'' because that phrase is repetitive; the term ''includes'' means that the list that follows is a non-exhaustive list of examples.

Comment: Some commenters suggested that CMS include additional specificity in the definition of expertise in health expertise, such as clinical experience practicing in underserved and marginalized communities, as well as lived, community, and professional experience in addition to academic training. Other commenters suggested that the individual be a physician. A commenter suggested CMS include in expertise in health equity include, ''experience serving on Health Equity Technical Expert Panels convened by CMS contractors.'' A commenter proposed that CMS require two members with expertise in health equity. A commenter suggested the health equity expert be required to undergo bias training. A commenter suggested that CMS clarify that the individual with expertise in health equity can be a nonphysician clinician, data analyst, or researcher. A commenter suggested CMS define expertise in terms of time, *i.e.,* five years of experience.

Response: CMS appreciates the suggestions for additional credentials and qualifications for the member of the UM committee with expertise in health equity. At this time, we do not believe adding the additional examples suggested by commenters of expertise in health equity to the non-exhaustive list in the regulation would necessarily add clarity, and we believe there is value in leaving some flexibility for MA organizations to determine what qualifies as expertise in health equity. Furthermore, CMS clarifies that the individual with expertise in health equity may include but not be limited to a nonphysician clinician, data analyst, or researcher. We are not adopting the recommendation to require bias training for the committee member with expertise in health equity because we did not propose additional requirements for specific committee members and do not feel it is necessary at this time. We also decline to adopt the recommendation to require the UM committee to have two members with expertise in health equity at this time because we believe that one member is sufficient to ensure utilization management policies and procedures are reviewed from a health equity perspective. However, we will continue to monitor implementation and compliance to determine if additional requirements, including adding additional members to the committee or specific training requirements, are necessary for future rulemaking.

Comment: Some commenters requested that MA organizations be permitted to use existing committee members, or employees of the MA organization, who have relevant qualifications to fulfil the role or leverage existing committees, if appropriate. A commenter asked CMS to clarify that plans can meet the requirement by recruiting a new member.

Response: As finalized, § 422.137(c)(5) requires MA organizations to include at least one member on the UM committee with expertise in health equity. The regulation does not set a minimum or maximum number of UM committee members so long as the composition requirements in § 422.137(c) are met; therefore, an MA organization leverage existing committee members or recruit a new member for the UM committee, as long as all regulatory requirements are met for the UM committee to include at least one member with expertise in health equity beginning January 1, 2025.

Comment: A few commenters recommended the member with expertise in health equity not be affiliated with the MA plan.

Response: At this time, CMS declines to require that the UM committee member with expertise in health equity not be affiliated with the MA organization (or the various MA plans offered by the MA organization). The regulation at § 422.137(c)(2) already requires that the UM committee include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan. CMS believes there is value in allowing flexibility at this stage and will monitor how this requirement is implemented to determine if additional requirements may be necessary in the future.

Comment: A commenter requested CMS delay the addition of a member with expertise in health equity.

Response: Given the flexibilities afforded plans regarding the ability to recruit a member with expertise in health equity, CMS does not believe an adjustment in the timeline is needed. We continue to believe that reviewing and analyzing UM policies from a health equity perspective serves as an important beneficiary protection and will evaluate the impact of this rule and consider all suggestions for future rulemaking. At the time that this final rule is issued, there are at least 6 months for an MA organization to ensure that its UM committee(s) include at least one member with health equity expertise to meet the January 1, 2025, deadline.

Comment: A commenter questioned whether there is sufficient evidence that adding such a role to this process will indeed improve health equity.

Response: CMS does not believe that a body of research or other formal evidence is necessary to justify the requirement that at least one UM committee member have expertise in health equity. The purpose of this requirement is to help ensure that all utilization management policies and procedures are reviewed from a health equity lens, and that the member of the committee with expertise in health equity provides final approval of the health equity analysis.

Comment: A commenter urged CMS to issue clear explanatory guidelines to ensure plan compliance.

Response: CMS believes that the requirements laid out in the regulation are sufficiently clear regarding what is necessary for compliance with this rule, including what constitutes expertise in health equity. However, CMS will monitor compliance and may issue additional guidance as necessary.

Comment: A commenter expressed that the entire UM committee, not just the member with health equity expertise, should be responsible for ensuring the analysis is comprehensive and complete.

Response: CMS expects that every member of the UM committee will participate in the production, review, and analysis of the health equity analysis, just as every member of the UM committee is responsible for reviewing all UM policies and procedures to ensure that they are kept up to date. However, just as the medical director is responsible for the overall actions of the UM committee itself, CMS believes it is important that the member of the UM committee with expertise in health equity will provide the final approval of the report in order to ensure the report is specifically reviewed from a health equity perspective.

Comment: Regarding the proposal to require the UM committee to conduct an annual health equity analysis of the use of prior authorization, commenters generally expressed support for the goal to advance health equity, increase transparency around the use of prior authorization, and ensure enrollees have timely access to medically necessary and clinically appropriate care. Some commenters did not support the proposal but did not elaborate as to their specific reasons for not supporting it. Some commenters encouraged CMS to continue advancing broader policy efforts to advance health equity goals

and expressed concern that the proposed analysis will not actually advance health equity or help identify gaps in health equity. A few commenters indicated the analysis could be helpful in assisting researchers to develop tools and conduct studies to further inform the public. Some commenters indicated that the UM committee may not be the best entity to conduct this analysis.

Response: CMS appreciates the feedback provided, as well as the support for the intent of the proposal. We also understand and agree with the sentiment that CMS should continue broader efforts to advance health equity. The goal of this proposal is to ensure that all utilization management policies and procedures are reviewed from a health equity perspective, and to establish baseline data by beginning to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified social risk factors. Because § 422.137 requires the UM committee to review any UM policies and procedures (including prior authorization) before an MA organization may use them beginning January 1, 2024, the UM committee is uniquely positioned to have access to data about when and how prior authorization policies and procedures are used by each MA plan offered by the MA organization in order to perform the health equity analysis and to use and report on the metrics we proposed and are finalizing at § 422.137(d)(iii).

This policy for the UM committee to perform and publicly post a health equity analysis with the information on specific prior authorization metrics, calculated using specific social risk factors, is just one piece of a much larger comprehensive approach to advancing equity for all, and we will continue to work to advance health equity. We will also consider all feedback received while working to develop future policy.

Comment: Some commenters indicated that prior authorization denial rates are not necessarily attributable to or correlated with an enrollee's social risk factor status. Commenters expressed concern about the proposed methodology and the practical utility of the data in its proposed form, and concerns about the potential for this information to mischaracterize plan activities or inadvertently mislead enrollees. Other commenters stated that comparing prior authorization metrics across MA plans cannot be done accurately given variation in how plans code and track prior authorizations. Therefore, the analysis should include explanatory info or methodological adjustments to account for varying conditions across populations.

A commenter requested that plans should automatically be required to explain their rates of denials for services that meet coverage rules. Some commenters requested general prior authorization utilization management reforms. Some commenters suggested that rather than create new data flows, CMS expand current part C data reporting requirements to include data elements specific to enrollees with the specified SRFs. Some commenters expressed concern that the number of enrollees with the SRFs enrolled in an MA plan (either too high or too low) could cause a comparison to be inaccurate. Several commenters expressed concern over ensuring that appropriate context for results of the analysis is available and not confusing or misleading for the public. Commenters also expressed concern that while making these results publicly available could increase accountability of MA organizations, CMS should also recognize that the amount of information enrollees must process, and that this data may not be useful or easy for a layperson to understand; therefore, commenters suggested that MA plans be required to include an executive summary posted with the report. A few commenters pointed out that for MA organizations that serve 100 percent limited-income subsidy/dual-eligible populations, these MA plans could be asked to publicly report the same metrics twice, since the ''Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (CMS–0057–F) rule has been finalized to require reporting of certain information about prior authorization metrics.

Response: CMS understands the concern about appropriate interpretation of the data. The regulation we are finalizing in this rule requires the health equity analysis for informational purposes only, to help gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs and allow MA plans and CMS to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs. CMS believes this required analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization. Since we currently do not have any information that compares data for enrollees with the specified SRFs to those without the specified SRFs, CMS continues to believe that this analysis is an important first step in looking deeper into the use of prior authorization and its potential effects on enrollees.

CMS appreciates the concern that enrollees already must process ample information when making plan decisions and that, as proposed, the information may not be easily comprehended or put into full context by a layperson, and will take these suggestions into account when issuing operational guidance for the format of the report. Further, we believe that by making this information easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans. We also believe that since the required data must be aggregated for all items and services at the plan level, the resulting analysis, while comprehensive, will not be overwhelming to the public. While CMS is not requiring the health equity report for each MA plan to include an explanatory statement or executive summary with the analysis at this time, if MA organizations wish to provide additional context for the results of the analysis of their MA plans, they may provide clarifying information in the report, provided that any such accompanying language is not misleading.

Regarding concerns that comparing prior authorization metrics across MA plans cannot be done accurately given variation in how plans code and track prior authorizations, CMS does not believe this presents a significant issue, since there is not a requirement in this rule for comparison across plans. The ''Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health

Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (CMS–0057–F) final rule (hereinafter referred to as the ''2024 Interoperability Final Rule''), which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758), adopted, among other provisions related to exchanges of certain health information and prior authorization processes, requirements for MA organizations and certain other payers (State Medicaid agencies, State CHIP agencies, Medicaid managed care plans, CHIP managed care plans, and QHPs on Federally facilitated Exchanges) to report certain metrics about prior authorization beginning in 2026.[105] The 2024 Interoperability Final Rule requires reporting of this information:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan, or issuer, for expedited prior authorizations, aggregated for all items and services.

[105] The 2024 Interoperability Final Rule is available online here: *govinfo.gov/content/pkg/FR-2024-02-08/pdf/2024-00895.pdf*. The regulations requiring reports of prior authorization performance metrics are 42 CFR 422.122(c), 440.230(e)(3), 438.210(f), 457.732(c), and 457.1230(d) and 45 CFR 156.223(c).

The performance metrics for the reporting under § 422.122(c), as adopted in the 2024 Interoperability Final Rule, and the reporting metrics adopted in this final rule at § 422.137(d)(6) use the same general categories, except that the 2024 Interoperability Final Rule requires that the information be aggregated for all enrollees, reported at the contract level, and excluding any drug coverage, while this final rule requires the reported information to be by groups with and without the specified social risk factors, reported at the plan level, and for all covered benefits (also excluding Part B drugs and OTC drugs covered by the MA plan and Part D drugs covered under the Part D benefit). The specified social risk factors are (i) receipt of the Part D low-income subsidy or being dually eligible for Medicare and Medicaid and (ii) having a disability, determined using information specified in § 422.137(d)(6)(ii)(B). Because the reporting is not for identical populations, these two separate regulatory reports will not be duplicative, and we believe that they will be complementary by providing information about the same prior authorization metrics for different populations. In addition, excluding drugs—Part B drugs, OTC drugs covered by the MA plan, and Part D drugs—for both lists should help address concerns about burden. To clarify this aspect of the scope of § 422.137(d)(6), we are finalizing additional language to exclude drugs from the scope of the new reporting and health equity analysis metrics; as finalized, § 422.137(d)(6)(iii) provides that the data used for this analysis and reporting excludes data on drugs as defined in § 422.119(b)(1)(v). Further, because MA organizations should already be collecting the data at the plan level, they should be able to report it with the stratification by SRFs for the requirements of § 422.137(d)(6), and then can aggregate that data up to the contract level for the reporting required by the 2024 Interoperability Final Rule. Therefore, having the specific metrics be the same (but reported for different populations) should ease the burden on MA organizations in gathering, validating, and formatting the data.

Comment: CMS solicited comment on additional populations to consider including in the health equity analysis. Several commenters indicated that the populations proposed in the analysis should be expanded, and many commenters suggested additional populations for CMS to consider, including: Members of economically marginalized communities; Original Reason for Entitlement Code for ESRD; individuals who receive SSBCI; individuals who have visited the ER in the past year; individuals who were hospitalized and sought post-acute care; individuals with limited English proficiency; individuals with mental health conditions, including depression, anxiety, and substance use disorder; individuals with chronic diseases such as asthma, COPD, cancer, obesity, cardiovascular disease, and diabetes; individuals with a combination of chronic conditions/diseases; individuals with a rare disease; members of racial and ethnic communities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; members of rural communities; persons otherwise adversely affected by persistent poverty or inequality; formerly incarcerated individuals; veterans; and individuals experiencing homelessness. A commenter suggested CMS take an intersectional approach—considering how multiple identities intersect and manifest experiences. A commenter asked CMS to consider using the publicly available Vizient Vulnerability Index™, which identifies social needs and obstacles to care that may influence a person's overall health. A few commenters suggested the enrollee data should be separated into full/partial dually eligible for Medicare and Medicaid. A commenter suggested that CMS align its approach with the NCQA from a population health management approach.

Some commenters acknowledged that adding populations to the analysis is not feasible at this time, because neither MA plans nor CMS has access to this data. Further, several commenters pointed out that reporting on many of the additional populations suggested would present issues because this type of demographic information would have to be self-reported, which could lead to incomplete and skewed data collection. Some commenters suggested that plans could collect this data upon enrollment. Generally, plans indicated that CMS should not add populations to the annual health equity analysis until data collection and methods for collecting demographic information have been piloted, tested, and found to be reliable in the context of the MA population. A commenter requested that CMS assist plans in gathering this information.

Response: CMS appreciates the feedback and input regarding additional populations to consider including in the health equity analysis. We acknowledge that there are challenges associated with collecting data in a consistent manner, and that not all populations can be

reliably identified using available data elements due to a lack of standardization in collection methods. Since much of this information would have to be self-reported, we agree this could lead to a potentially inconsistent or misleading analysis. For that reason, we are not adding additional populations at this time. We will take all suggestions into consideration for future rulemaking and continue to explore ways to expand the populations included in the health equity analysis. We also urge MA plans to consider how data on some of the proposed populations could be collected and analyzed.

Comment: Some commenters pointed out that CMS's proposed method of determining disability status could leave out enrollees who are over the age of 65 and have a disability but did not originally qualify for Medicare on that basis.

Response: The variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems is the method used to determine disability status for the Health Equity Index and Categorical Adjustment Index. At this time, CMS believes that it is necessary to maintain consistency in identifying MA enrollment populations by this social risk factor for the Star Ratings and the UM committee's health equity analysis. However, we also understand the concern raised by commenters and will continue to evaluate how we could expand the ways we identify individuals who have a disability.

Comment: CMS requested comment on any specific items or services, or groups of items or services, subject to prior authorization that we should consider disaggregating in future rulemaking. Many commenters provided suggestions and feedback. Several commenters asserted that because the proposed analysis would consist of prior authorization metrics aggregated for all items and services, it will not provide enough detail for true accountability and could allow plans to hide disparities. Commenters recommended that CMS require a further level of granularity to ensure that potential disparities could be identified. Specifically, commenters suggested that CMS require disaggregation by item and service to ensure that CMS can identify specific services that may be disproportionately denied.

Commenters also provided suggestions for specific items and services for CMS to consider for disaggregation, including: Additional modalities beyond drugs/services that require prior authorization such as diagnostic tests, durable medical equipment, and skilled nursing facility care; substance use disorder and mental health services so these can be compared to medical services; prescription drugs; service category for rehabilitative services; physical therapist services; kidney care services, including dialysis treatments and transplant; prosthetics, orthotics and supplies; cellular and/or tissue-based products (CTPs, or skin substitute) services, in-office injections, in-office medically necessary imaging, ankle-foot orthoses (AFOs) for traumatic conditions, surgical dressings, and biopsy of suspicious lesions; disaggregated data on access to medically necessary post-acute care which should include LTCHs, IRFs, SNFs, and HHAs. A commenter suggested that CMS require MA plans to submit the data underlying the report, disaggregated with demographic and other health equity indicators that would allow CMS to conduct more flexible analysis and compare subpopulations within plans. CMS could then aggregate and provide searchable results across MA plans, including by original reason for entitlement code and by age group. A commenter requested that MA plans should have discretion to determine when disaggregating will provide meaningful information and not compromise the privacy of its members.

Response: CMS thanks commenters for their suggestions and feedback. We agree that disaggregation of the reported metrics by specific benefit could assist in increasing transparency and ensuring the most accurate data regarding prior authorization is available. As of now, it is our intent to require some level of disaggregation in the coming years, and we will consider all suggestions for any future rulemaking. We also believe there is significant value in establishing baseline data, since there is currently very little publicly available information regarding the use of prior authorization and its potential impact on specific populations. We believe that at least during the initial year, the analysis as proposed strikes a balance between providing information that may be useful to CMS, MA plans, and the public, and not providing an overwhelming amount of information.

Comment: Some commenters suggested that disenrollment data be included among the required metrics for the health equity analysis. Commenters relayed that this is important since prior authorization can lead individuals with complex health conditions and disabilities to disenroll from a plan after receiving a prior authorization decision. A commenter suggested that, in an effort to further identify disparities and advance health equity through conducting this analysis, CMS also include one or more of the following four criteria recognized by the National Committee for Quality Assurance as baseline to begin accounting for equitable outcomes: Select indicators of social determinants of health; Select a reference group (a ''standard'' comparison group independent of the data vs. the data informing the comparison group); Select health care quality metrics. These could include composites (*e.g.,* vaccination rates, quality measures, infant mortality rates); Use benchmarks (*e.g.,* compare results to national estimates). Another commenter suggested that CMS analyze if and how often providers decline to prescribe a treatment because they do not have the resources to engage in a prior authorization process. Several commenters suggested the analysis include the reason for which a prior authorization request was denied. A commenter suggested that MA plans report prior authorizations as a part of encounter data so that CMS and independent researchers can conduct unbiased analyses of the equity impacts of utilization management. Another commenter suggested MA plans target specific service types that are frequently subjected to inappropriate utilization review practices. A commenter proposed requiring plans to report whenever end-of-life status is the reason for denying a prior authorization. A commenter recommended comparing sub-populations enrolled in D–SNPs versus those enrolled in non-SNP MA plans. Another commenter recommended comparing appeal rates and outcomes on denied PA requests between populations. A commenter suggested that such analytics should include a side-by-side comparison of all data points by MA plan and compare them to traditional Medicare and Medicaid coverage; and that the MA plan should be required to provide criteria used to determine medical necessity and authorizations and include post-payment audit data in addition to prepayment authorization outcomes in the posted information and health equity analysis.

Response: CMS appreciates the feedback, and while we are not adding additional metrics to the analysis at this time, we will consider doing so in future rulemaking. We would also direct commenters to the 2024 Interoperability

Final Rule, which adopts certain procedural and timing requirements for prior authorizations and several API requirements for MA organizations and other impacted payers, including implementation of a Prior Authorization API, new reporting to CMS, and new requirements to provide to the applicable provider a specific reason for the denial of a request for prior authorization.

Comment: CMS requested comment on requiring MA plans to submit a link to their health equity analysis directly to CMS. Many commenters supported the addition of this requirement. Commenters further suggested that CMS make the specified metrics to be used in the analysis publicly available on the CMS website and to require MA plans to publish the results of the analysis in plain, easy to understand language that can be understood by the average enrollee. A commenter requested the results of the analysis be accessible on the Medicare Plan Finder on *www.medicare.gov* so that beneficiaries can evaluate the ease with which they may access services when determining which health plan to choose.

Additionally, several commenters also suggested that plans only submit a link to CMS, and not post the report publicly. These commenters generally stated that proposed requirement to post the report publicly on plan sponsors' websites could cause unnecessary confusion to providers and beneficiaries who can easily misinterpret publicly available prior authorization metrics. Further, because providers and enrollees are not consistent across MA plans, commenters pointed out that it may be challenging to compare metrics across plans. Some commenters suggested using Part C reporting requirements instead of the proposed analysis to collect the data.

Some commenters suggested that CMS should establish a unified portal where stakeholders can view all MA plans' health equity analyses and require certain standardized reporting to improve stakeholders' ability to compare health equity impacts across MA plans.

Several commenters requested that CMS first create a standard system of reporting before requiring a publicly reported analysis.

Response: At this time, we will not require plans to submit a weblink to their health equity analysis to CMS. However, we will continue to evaluate whether this is necessary, and may add such a requirement in future rulemaking. We disagree that requiring the health equity analysis be published directly on the MA plan's website could be confusing for enrollees. We believe that many individuals use the MA plan's website as a primary resource for information on that specific plan and would therefore be more inclined to visit the MA plan's website to learn about that plan. We are finalizing as proposed the requirements in § 422.137(d)(7) that the MA organization must publish the results of the health equity analysis (which must use the metrics specified in § 422.137(d)(6)) on the plan's website meeting requirements for public access listed in paragraphs (d)(7)(i) through (iv). Regarding the concern that metrics cannot be compared across MA plans, we are not requiring a comparison of metrics across MA plans at this time. Rather, the goal of the analysis and public reporting is to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs within individual MA plans. However, the accessibility of these reports in .txt file in the root directory of the website domain that includes a direct link to the machine-readable file and with the data contained within that file being digitally searchable and downloadable are intended to ensure automated access to the data. This may facilitate comparisons of the data across plans.

Comment: Several commenters requested CMS clarify that the data elements reporting the average and median time elapsed should be calculated beginning with the time the MA plan has received all the necessary information to complete the prior authorization request. Commenters indicated that, often, prior authorization requests are initially denied, or may be delayed, because information necessary to complete the request is missing. Some commenters also expressed concern over whether and how to count enrollees who have not been enrolled in the MA plan for a full year, and one commenter asked how to account for enrollees whose social risk factors may change over time.

Response: The average and median time that elapsed between the submission of a request and a determination by the MA plan should be calculated based on when the initial request is made. Since the goal of this analysis is to collect baseline data and gain a clearer picture of the impact of prior authorization on enrollees with the specified social risk factors, it is pertinent for CMS and the public to understand how long the entire process takes. This includes when MA plans need additional information from providers to make decisions. Regarding counting enrollees who have been enrolled for less than a full year, MA plans must count these enrollees—the point of the analysis is to analyze the use of prior authorization, therefore an enrollee's time in the plan when the prior authorization request is processed is not relevant. Further, CMS does not believe that enrollees whose SRF status may change over time is an issue since again, the point of the analysis is to analyze the use of prior authorization and begin to understand any correlation between the use of prior authorization and the presence of the social risk factors. If an enrollee's SRF status changes throughout the plan year, that should not have an impact on how the analysis is conducted, because CMS expects the plan to use the enrollee's status at the time the prior authorization is processed for calculating the specified metrics.

Comment: Several commenters asked that CMS explain how it plans to use the information included in these health equity analyses, including how it may be used to help inform future policies and whether CMS will take enforcement action based on the results of the analysis. Some commenters expressed concern that the health equity analysis would be used as a mechanism to penalize MA plans. A commenter requested that plans be permitted to create solutions should inequalities be identified. A few commenters suggested that CMS factor the data produced by the analysis into determinations for 2027 Star Rating Health Equity Index rewards.

Response: At this time, CMS plans to use the health equity analysis for informational purposes, to allow MA plans and CMS to begin to identify whether the use of prior authorization correlates to any persistent disparities among enrollees with the specified SRFs. CMS is not imposing additional requirements currently, and will take all comments received, as well as the results of the initial health equity analysis, into account when considering future policymaking and guidance. This analysis is just one step in continued and ongoing efforts to ensure all enrollees have safe and equitable access to medically necessary services.

Comment: CMS solicited comment on alternatives to the July 1, 2025, deadline for the initial health equity analysis to be posted to an MA plan's publicly available website. Several commenters suggested that CMS adopt an alternative timeline for publication of the initial report. Some commenters suggested that CMS first work with MA plans to standardize data collection and reporting, or that CMS develop a standard template for MA plans to use.

Other commenters indicated that issuing the initial report in July 2025 could present challenges for plans' IT resources, especially for smaller plans. Some commenters requested that MA plans submit their reports to CMS in 2025, and that CMS provide confidential feedback during the initial year and use that time to determine whether the results of the report are useful. Then in 2026, MA plans report results publicly. Further, commenters indicated that a 2026 date for publication of the initial report would allow plans to collect a full year of data. A commenter suggested CMS extend data back over several contract years. A commenter expressed that for plans to publish a health equity analysis that is in a machine-readable format (MRF) with the data contained within that file being digitally searchable and downloadable, it will require CMS to develop an industry wide MRF schema, which will likely take longer than is provided for in the proposed rule.

Response: CMS understands the processes and resources required to produce a new reporting requirement, however since MA plans should already have the relevant data available, as they are currently conducting the prior authorization process. Therefore, CMS declines to adapt an alternative timeline for the report. Since the goal of this analysis is to begin to understand the potential impact of prior authorization on enrollees with the specified social risk factors, any level of information that is made publicly available will be useful at this stage. Regarding CMS's production of an MRF schema, CMS does not believe that this will require extending the timeline for the initial report due date, since as outlined in the preamble, CMS plans to issue guidance describing the format to be used by MA plans. CMS declines to extend the data collection back over several contract years.

Comment: Several commenters suggested that the health equity analysis be extended to cover step therapy and Part B drugs.

Response: CMS thanks commenters for this suggestion and will consider it for future policymaking.

Comment: Some commenters suggested that CMS extend the analysis to include all types of utilization management, not just prior authorization.

Response: CMS thanks commenters for this suggestion and will consider for future rulemaking.

Comment: Several commenters suggested the CMS establish a parallel health equity structure for Part D plans, including similar health equity related requirements for the composition and consideration of Pharmacy & Therapeutic (P&T) Committee, and make regulatory changes to the part D provisions.

Response: While this comment is out of scope for the current rulemaking, CMS thanks commenters for their feedback and will take it under consideration for future rulemaking.

Comment: A commenter requested that CMS provide a uniform definition for the specified social risk factors.

Response: As outlined in the preamble and provided in § 422.137(d)(6)(ii) (as proposed and finalized), the specified social risk factors are defined as follows: (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS chose these SRFs because they mirror the SRFs that will be used to measure the Heath Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and we believe it is important to align expectations and metrics across the program.

MA plans can access the relevant information through the Beneficiary Eligibility Query (BEQ), which is a pre-enrollment query MA plans use to check eligibility prior to enrolling an individual. The BEQ provides enrollee information including demographics, entitlement/eligibility, Part D employer subsidy, and Low-Income Subsidy. MA plans can submit a BEQ query by submitting their requests in a batch file via CMS Enterprise File Transfer (EFT). MA plans can also perform the query online using the MARx, which provides real time information regarding eligibility. MARx provides MA plans with data related to enrollees and their subsidies.

Comment: A commenter cautioned that some of the information gathered as part of a health equity analysis may be confidential or proprietary to the MA plan and, therefore encouraged CMS to permit the plan to withhold confidential and proprietary information included in these analyses from publication.

Response: CMS declines this suggestion. Given the nature of the report, and that all information must be aggregated, CMS does not believe there is a risk for proprietary information to be disclosed. However, CMS will permit MA organizations to suppress information for small cell sizes in instances where the MA plan's service area is so small, that even in the aggregate, the presentation of the data in the analysis could disclose confidential data about covered individuals.

Comment: A commenter requested clarification that the intent is for the link in the footer of the website to go directly to the analysis file, or, if would it be acceptable for the link to direct to a landing page that may contain multiple health equity related reports so long as the analysis remains easily accessible.

Response: It would be acceptable for the link in the footer of the website to direct to a landing page, so long as the analysis remains easily accessible. This means that the report for each MA plan must be clearly labeled, and readily accessible to interested parties and other members of the public.

Comment: A commenter recommended regulatory language to include requirements for the standard exchange of the data among payers, providers or healthcare community such as USCDI version 3.

Response: CMS thanks the commenter for the suggestion but declines to incorporate such a standard at this time.

We thank all commenters for their comments. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, as previously summarized, we are finalizing the modifications to § 422.137 substantively as proposed but with two revisions. First, we are not finalizing use of the repetitive phrase ''but is not limited to'' in the sentence that provides the non-exhaustive list of examples of expertise in health equity. Second, we are finalizing a clarification in § 422.137(d)(6)(iii) that the data used for the health equity analysis and reporting excludes data on drugs as defined in § 422.119(b)(1)(v).

V. Enrollment and Appeals

A. 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 ''special needs individuals,'' as defined at section 1859(b)(6)(B) of the Act, and which includes institutionalized individuals, dually eligible individuals, and individuals with severe or disabling chronic conditions. Only those

individuals who qualify as special needs individuals may enroll, and remain enrolled, in an SNP. In the January 2005 MA final rule, we established at § 422.52 that individuals were eligible to enroll in an SNP if they: (1) met the definition of a special needs individual, (2) met the eligibility requirements for that specific SNP, and (3) were 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 SNP, 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 enrollees are given adequate notice prior to being disenrolled from an SNP and provided an opportunity to prove that they are eligible to remain enrolled in the plan, if applicable. Providing these enrollees 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 enrollees 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 interested parties, we proposed to codify current policy for MA plan notices prior to disenrollment for loss of special needs status, as well as a final disenrollment notice. We intend that interested parties will be able to rely on these regulations, establishing the procedures that an MA organization must follow in the event that an SNP enrollee loses special needs status and is disenrolled from the SNP on that basis. Specifically, we proposed to revise § 422.74(d) by redesignating paragraph (d)(8) as paragraph (d)(9) and adding a new paragraph (d)(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 such enrollee 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. Such disenrollment effective date 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. Additionally, the final notice of involuntary disenrollment must be sent before submission of the disenrollment to CMS. Lastly, we proposed in new paragraph (8)(iv), that the final notice of involuntary disenrollment 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.

These proposed changes would codify longstanding guidance. 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 Fund.

We received the following comments, and our responses follow.

Comment: A commenter expressed support for this provision.

Response: We thank the commenter for their support of our proposal.

After consideration of all public comments and for the reasons outlined in the proposed rule and here, we are finalizing our proposal without substantive changes, but with minor changes for clarity.

B. Involuntary Disenrollment for Individuals Enrolled in an 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 an 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'' which appeared in the **Federal Register** on June 26, 1998 (63 FR 34968), we established the conditions for MA organizations to enroll individuals in an 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 an 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 MMA, 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 proposed 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 such enrollee 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 also proposed 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)(3). 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 proposed 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.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

C. 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 a 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.[106] 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 sets forth that MA and PDP plans are 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 interested parties, we proposed 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 proposed that the

[106] This guidance can be 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.

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 concluded that the requirements have been previously implemented and are currently being followed by plans. There is also no impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: A commenter requested that CMS provide a model letter for this required notice.

Response: We thank the commenter for the suggestion. We have longstanding model reinstatement notices that have been displayed in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A commenter expressed that they currently send reinstatement letters and recommended this process continues. The commenter also noted that beneficiary history in MARx is typically removed when reinstatement situations occur and is concerned about how plans will know when the enrollment issue has happened.

Response: We appreciate the commenter's feedback. This proposal does not change the existing sub-regulatory guidance for plans to provide notification of enrollment reinstatement based on a beneficiary's cancellation of a new enrollment in a different plan. The plan can continue to send reinstatement letters to beneficiaries. We also note that the new plan receives a transaction reply code (TRC) 15 in MARx—which describes CMS's response to the enrollment transaction—when the enrollment is removed from a beneficiary's record. The plan in which the beneficiary's enrollment is being reinstated receives a TRC 287 if there are no changes to the beneficiary's profile from the time of the disenrollment to the time of the cancellation.

Comment: A commenter expressed support for this proposal.

Response: We thank the commenter for their support of this proposal.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor modifications to clarify the regulation text proposed at § 423.32(h).

D. 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 set forth 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 35074). This requirement was codified at § 422.66(b)(4) and has remained in place for MA organizations.

Current Part D regulations, however, do not impose requirements for Part D sponsors that fail to submit the transaction notice to CMS in a timely manner. 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 interested parties, and to align the Part D regulation with the requirements for MA organizations, we proposed 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 concluded 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).

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal with one minor modification. We are making a technical correction to the regulation text proposed at § 423.36(f) to update a cross-reference that is inaccurate, changing ''paragraph (c)(1)'' to ''paragraph (b)(1)''.

E. 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 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), the regulations 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, as well as send a copy to the enrollee which informs 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 for the period 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 (70 FR 4211). 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, at 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, the procedural steps for plans to address incomplete disenrollment requests. These steps include providing that when the disenrollment request is incomplete, plans must document 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 interested parties about the MA and Part D programs and about the requirements applicable to requests for voluntary disenrollment from MA and Part D plans, we proposed to codify CMS's longstanding policies 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 at new paragraphs §§ 422.66(b)(6) and 423.36(d). The specified timeframes are described at proposed §§ 422.66(b)(3)(v)(C) and 423.36(b)(4)(iii). We also proposed, 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 proposed that 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 proposed 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 proposed that if any additional information needed to make the disenrollment request complete is not received within these timeframes, the disenrollment request must be denied.

This proposal codifies longstanding guidance. 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 concluded that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

We received the following comment, and our response follows.

Comment: A commenter expressed support for this provision.

Response: We thank the commenter for their support of our proposal.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal without modification.

F. Reinstatement of Enrollment for Good Cause (§§ 417.460, 422.74 and 423.44)

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 grace 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 21432) 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 22072), 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 interested parties, we proposed 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 proposed 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 concluded 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.

We received the following comment, and our response follows.

Comment: A commenter expressed concern about requiring disenrolled individuals to request reinstatement within the 60-calendar day period following the date they are disenrolled from the plan. The commenter states that contacting the plan within the 60-day period to request reinstatement will be challenging for people with a mental health or substance use disorder (MH/SUD), adding that people with a MH/SUD often do not complain when they face administrative difficulties.

Response: While we agree that taking action to request reinstatement following disenrollment may be more challenging for some than it is for others, we believe that 60 days is a sufficient amount of time and that it is not unreasonable to ask someone who has been disenrolled from their plan and, as such, is no longer being covered, to reach out to the plan and request reinstatement within the 60-day period following disenrollment. We require that all MA and Part D plans offer a minimum two-month grace period prior to disenrolling someone who has not paid their plan premium; many plans offer a longer grace period. This minimum two-month period prior to disenrollment, combined with the 60-day period following disenrollment to request reinstatement for good cause, provides a reasonable amount of time for someone who wishes to continue their enrollment in the plan to take action to resolve the premium delinquency and, if disenrolled, make a reinstatement request.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor modifications to reorganize and clarify the regulation text proposed at §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi).

G. 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 who 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). (For this section and throughout 42 CFR 417, CMP is used to mean competitive medical plan, not civil monetary penalties.) In implementing regulations which appeared in the **Federal Register** on September 1, 1995 (60 FR 45679), 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 34968), 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 enrollee 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 at § 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 ''abusive.'' 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 enrollees 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 enrollee'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 notices that an MA organization, Part D sponsor, and cost plans must send before requesting permission from CMS to involuntarily disenroll the individual.

To provide transparency to interested parties and stability as to the operation of the program, we proposed to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. These notices provide the enrollee with a warning of the potential consequences of continued disruptive behavior. In a new proposed paragraph at § 422.74(d)(2)(vii), we proposed to codify existing policy currently set out in sub-regulatory guidance regarding MA plan notices prior to 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 enrollee 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 individual, sent at least 30 days after the advance notice to give the enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 422.74(c). We also proposed 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 addition 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 proposed to codify existing policy currently set out in sub-regulatory guidance regarding PDP sponsor notices prior to 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 enrollee that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the individual, sent at least 30 days after the advance notice to give the enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 423.44(c). We also proposed 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 (d)(2)(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 proposed to codify existing policy guidance currently set out in sub-regulatory 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 enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 417.460(e)(6). We also proposed 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 proposed in § 417.460(e)(2) that, as part of its efforts to resolve the problem presented by the enrollee, an 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.

This proposal codifies longstanding guidance. 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 concluded that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal with slight modifications to reorganize the regulation text for additional clarity.

H. 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 who 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 ground for termination 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 who 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 proposed 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 was to codify the current policy, as reflected in section 50.3.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

We proposed 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 § 423.44(d)(9), the Part D plan has the option to involuntarily disenroll the individual. Further, we proposed to establish at such new paragraph § 423.44(d)(9) the process for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card. We proposed 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, to be provided at §§ 423.44(d)(9)(i)(A) and 423.44(d)(9)(i)(B), respectively. We proposed to establish at § 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 proposed 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 further proposed to add a new § 423.44(d)(9)(ii) to establish that a Part D plan that 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 also proposed 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 the Part D optional involuntary disenrollment for fraud and abuse regulations at § 423.44(d)(9)(i), 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. Since 2012, there have been only five disenrollments for fraud and abuse. Three of those disenrollments were from MA/MA–PD 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 these data, we do not expect any future impact to the Medicare Trust Fund.

We further proposed 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 proposed 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 written notice to the member and notifying CMS of the disenrollment have already been accounted for under OMB control numbers 0938–0964 (CMS–10141).

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

I. 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 regulations (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 proposed 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 at section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and Part D plan sponsors have previously implemented and are currently following such policy. We proposed, 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 proposed 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. This proposal is a codification of longstanding Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. These updates do not add to the existing disenrollment process, so we do not believe there is any additional paperwork burden.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing our proposal without substantive changes but with minor organizational and editorial changes in § 423.44(d)(1) for clarity.

J. 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, 85 FR 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 proposed to revise the end date(s) for the SEP for Government Entity-Declared Disaster or Other Emergency specified within §§ 422.62(b)(18) and 423.38(c)(23). As part of this proposal, we proposed to create a new § 422.62(b)(18)(i), and redesignate what is currently in § 422.62(b)(18)(i)–(iii) as (b)(18)(ii)–(iv); likewise, we proposed to create a new § 423.38(c)(23)(i) and redesignate what is currently in § 423.38(c)(23)(i)–(iii) as (c)(23)(ii)–(iv).

First, we proposed 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 ordinances or codes regarding the automatic expiration date of state or local emergency/disaster 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 proposed 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 sought 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 proposed 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 interested parties 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 Fund.

We received the following comments, and our responses follow.

Comment: Multiple commenters expressed support for this provision.

Response: We thank the commenters for their support of our proposal.

Comment: Multiple commenters suggested that we extend this SEP eligibility period to six months after the end of the incident period, to align with the timeframe of the Parts A and B SEP for disasters or emergencies, instead of the two months currently codified in regulations.

Response: We thank the commenters for their suggestion; however, these proposed changes were aimed to provide clarity on incident end dates in cases where automatic expirations were relied upon, or when no end date was identified. We believe that the two full calendar months after the end of the incident period, as currently codified, provides ample opportunity for beneficiaries to select and enroll in a new plan. Though the timeframe for the Parts A and B SEP for disasters or emergencies is six months, two months is appropriate for making a Parts C/D election, given the procedural differences in enrolling in Medicare for the first time and making a new C/D plan election. The two-month period is also consistent with our other Parts C/D SEPs. We also note that beneficiaries who are unable to make an election during this SEP because of continued impacts of the disaster or emergency may be eligible for the SEP for Other Exceptional Circumstances and should contact 1–800–MEDICARE to explain their unique situation.

Comment: A commenter expressed concern that individuals who use the Medicare Parts A and B Disaster/Emergency SEP to enroll in Premium Part A or Part B may not be able to use the MA or Part D Disaster/Emergency SEP given the different eligibility timelines between the A/B SEP and C/D SEP.

Response: In order to use the MA and Part D SEP for Government Entity-Declared Disaster or Other Emergency, the individual must have been eligible for another valid election period but was unable to utilize it because they were affected by a disaster or other emergency. Newly MA-eligible individuals, because of their A/B SEP election, do not meet this eligibility criteria and are thus not impacted by the different eligibility timelines between the A/B and C/D SEPs. Because their MA eligibility is as a result of using the A/B SEP, these individuals would not be eligible to use the MA and Part D SEP for Government Entity-Declared Disaster or Other Emergency because they were not eligible for another MA or Part D election period that they were unable to use due to the disaster or other emergency. We also note that individuals who do utilize the A/B Emergency SEP are eligible to use the SEPs newly codified at 42 CFR 422.62(b)(26) and 423.38(c)(34), and thus would have the ability to make a Part C/D election after taking advantage of their A/B SEP.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor edits at §§ 422.62(b)(18) and 423.38(c)(23) for grammar and clarity, as well as modifications to correctly redesignate existing paragraphs.

K. 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 an M+C, later known as 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 that in the continuation area enrollees have access to the full range of basic benefits under the original Medicare fee-for-service program option. In addition, section 1860D–1(b)(1)(B)(i) of the Act generally directs CMS to use rules for enrollment, disenrollment, and termination relating to residence requirements for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act.

In the June 1998 Interim Final Rule with Comment Period (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.

In January 2005, we published a final rule (70 FR 4194) to establish at § 423.30(a)(2)(ii) 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)(i) 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. Further, section 1860D–1(b)(1)(B)(iii) of the Act directs CMS to generally use rules related to coverage election periods that are similar to those established for MA organizations under section 1851(e) of the Act. In the June 1998 IFC (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) are 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. This guidance provides 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 proposed 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 was to codify current policy as reflected in CMS's existing sub-regulatory 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 interested parties 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 consecutive months.

If 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 U.S. Postal Service, 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 proposed to align the Part D regulation with the 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 proposed 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), respectively, if provided by mail, is returned to the plan sponsor by the U.S. 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 interested parties 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.

We received no comments on our proposal. Except for a minor change to the organization of the regulation text for 423.38(c)(7), we are finalizing the proposal without modification for the reasons outlined here and in the proposed rule.

L. 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 an 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. 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 sub-regulatory 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 proposed 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.

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 MA organizations and Part D sponsors, we believe that plans are complying with this guidance, and we did not propose 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.

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

M. 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 of such absence. 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 of such absence. 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 proposed 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 proposed 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 disenrollments 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 proposed 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 proposed 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, respectively, must document the basis for involuntary disenrollment actions that are based on the residency requirements.

The intent of our proposal was 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 documentation policy that is 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 already being carried out by MA organizations and Part D plan sponsors. Codifying these policies regarding notification of disenrollment and document retention will provide transparency and stability for interested parties 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.

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

N. 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 proposed to codify this existing policy to provide transparency and ensure consistency between the Part C and Part D programs. Specifically, we proposed 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 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 concluded 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.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

O. Drug Management Program (DMP) Appeal Procedures (§ 423.562)

We proposed a technical change at § 423.562(a)(1)(v) to 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 eliminates discretionary language and improves consistency with § 423.153(f), which requires each Part D plan sponsor to establish and maintain a DMP and include appeal procedures that meet the requirements of subpart M for issues involving at-risk determinations. This is strictly a technical change to the wording at § 423.562(a)(1)(v) and does not impact the underlying burden related to processing appeals of at-risk beneficiaries. This change 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 did not receive comments on this proposal. For the reasons outlined here and in the proposed rule, we are finalizing the proposal as proposed.

P. Revise Initial Coverage Election Period Timeframe To Coordinate With A/B Enrollment (§ 422.62)

Section 4001 of the Balanced Budget Act of 1997 (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act), establishing Part C of the Medicare program known originally as M+C and later as Medicare Advantage (MA). As enacted, section 1851(e) of the Act establishes specific parameters in which elections can be made and/or changed during enrollment and disenrollment periods under the MA program. Specifically, section 1851(e)(1) of the Act requires that the Secretary specify an initial coverage election period (ICEP) during which an individual who first becomes entitled to Part A benefits and enrolled in Part B may elect an MA plan. The statute further stipulates that if an individual elects an MA plan during that period, coverage under the plan will become effective as of the first day on which the individual may receive that coverage. Consistent with this section of the Act, in the ''Medicare Program; Establishment of the Medicare+Choice Program'' interim final rule with comment period which appeared in the **Federal Register** on June 26, 1998, (herein referred to as the June 1998 interim final rule), CMS codified this policy at § 422.62(a)(1) (63 FR 35072).

In order for an individual to have coverage under an MA plan, effective as of the first day on which the individual may receive such coverage, the individual must elect an MA plan before he or she is actually entitled to Part A and enrolled in Part B coverage. Therefore, in the June 1998 interim final rule CMS codified the ICEP to begin 3 months prior to the month the individual is first entitled to both Part A and enrolled in Part B and ends the last day of the month preceding the month of entitlement (63 FR 35072).

Section 102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised section 1851(e)(1) of the Act to provide for an ICEP for MA that ends on the later of, the day it would end under pre-MMA rules as described above, or the last day of an individual's Medicare Part B Initial Enrollment Period (IEP). This approach extended an individual's ICEP which helped to ensure that an individual who uses their IEP to enroll in Medicare Part A and B has the opportunity to elect an MA or MA prescription drug (MA–PD) plan following their first entitlement to Part A and enrollment in Part B. Consistent with the revised provisions of section 1851(e)(1) of the Act, CMS codified this policy at § 422.62(a)(1) in the Medicare Program; Establishment of the Medicare Advantage Program final rule which appeared in the **Federal Register** on January 28, 2005 (70 FR 4717).

As described in § 422.50(a)(1), eligibility for MA or MA–PD enrollment generally requires that an individual first have Medicare Parts A and B and meet all other eligibility requirements to do so. The ICEP is the period during which an individual newly eligible for MA may make an initial enrollment request to enroll in an MA or MA–PD plan. Currently, once an individual first has both Parts A and B, their ICEP begins 3 months immediately before the individual's first entitlement to Medicare Part A and enrollment in Part B and ends on the later of:

1. The last day of the month preceding entitlement to Part A and enrollment in Part B; or

2. The last day of the individual's Part B IEP.

Individuals who want to enroll in premium-Part A, Part B, or both, must submit a timely enrollment request during their IEP, the General Enrollment Period (GEP), or an existing special enrollment period (SEP) for which they are eligible. Eligible individuals may choose to enroll in both Part A and B during their first opportunity, that is, during their IEP. These individuals have an ICEP as described in § 422.62(a)(1)(ii), that is, they can choose to enroll in an MA plan (with or without drug coverage) at the time of, or after, they have both Part A and B, up until the last day of their IEP. However, not all individuals enroll in both Part A and B during their IEP. Other individuals, such as those who are working past age 65, may not have both Part A and B for the first time until after their IEP. These individuals may only have Part A and/or B for the first time when they use an SEP or a future GEP to enroll. To note, prior to January 1, 2023, individuals who enrolled in Part A and/or Part B during the GEP had a universal effective date of July 1st. These individuals had an ICEP as described in § 462.22(a)(1)(i), that is, the ICEP started April 1st and ended June 30th. Although these individuals had to decide whether to enroll in an MA or MA–PD plan prior to their July 1st effective date, they did have time to consider their options, as the GEP is January 1st–March 31st annually, and their enrollment in Part B, (and Part A if applicable), was not effective until July 1st. However, the Consolidated Appropriations Act, 2021, (CAA) (*Pub. L. 116–260*), revised sections 1838(a)(2)(D)(ii) and 1838(a)(3)(B)(ii) of the Act to provide that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement would begin with the first day of the month following the month in which they enroll. For

example, if an individual has Part A, but enrolls in Part B in March, during the GEP, they would first have both Part A and Part B effective April 1st. Although this provides for an earlier Medicare effective date, the individual's ICEP would occur prior to that Medicare effective date, that is, as described in § 422.62(a)(1)(i) above, and they no longer have that additional time to consider their options.

Currently, the individuals described above have an ICEP as described in § 422.62(a)(1)(i) and can only enroll in an MA plan (with or without drug coverage) *prior* to the effective date of their Part A and B coverage. For example, an individual's 65th birthday is April 20, 2022, and they are eligible for Medicare Part A and Part B beginning April 1, 2022. They have premium-free Part A; however, the individual is still working, and has employer health insurance, so they decide not to enroll in Part B during their IEP. The individual retires in April 2023, and enrolls in Part B effective May 1, 2023 (using a Part B SEP). The individual's ICEP would be February 1st through April 30, 2023. These individuals need to decide if they want to receive their Medicare coverage through an MA plan prior to the effective date of their enrollment in both Part A and B. In this example, the individual would have to enroll in an MA plan using the ICEP by April 30, 2023.

Section 422.62(a)(1) was intended to provide beneficiaries who enroll in both Part A and Part B for the first time with the opportunity to elect an MA plan *at the time* that both their Part A and B coverage were effective. However, in practice, individuals described above, who do not enroll in Part B during their IEP, do not have an opportunity to elect to receive their coverage through an MA plan *after* their Part A and B coverage goes into effect. When an individual enrolls in both Part A and B for the first time using an SEP or the GEP, they have to determine, prior to the start of their coverage, if they want to receive their coverage through Original Medicare or an MA plan prior to the effective date of their Part A and B coverage. If they do not use their ICEP to enroll in an MA plan prior to when their Part A and B coverage becomes effective, they lose the opportunity to enroll in an MA plan to receive their Medicare coverage and will generally have to wait until the next enrollment period that is available to them to choose an MA plan.

To provide more flexibility, we proposed to revise the end date for the ICEP for those who cannot use their ICEP during their IEP. That is, we proposed in § 422.62(a)(1)(i) that an individual would have an opportunity to enroll in an MA plan (with or without drug coverage) using their ICEP until the last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B. Under proposed § 422.62(a)(1)(i), the individual's ICEP would begin 3 months prior to the month the individual is first entitled to Part A and enrolled in Part B and would end on the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B. Using the example above, we are proposing that the individual's ICEP would be February 1st through June 30, 2023, instead of February 1st to April 30th. As described in § 422.68(a)(1), if an election is made prior to the month of entitlement in both Part A and Part B, the MA election would be effective as of the first date of the month that the individual is entitled to both Part A and Part B.

We believed that extending the timeframe for the ICEP under § 422.62(a)(1)(i) would provide beneficiaries that are new to Medicare additional time to decide if they want to receive their coverage through an MA plan. We believed that extending this timeframe would help those new to Medicare to explore their options and select coverage that best suits their needs and reduce the number of instances where an individual inadvertently missed their ICEP and has to wait until the next open enrollment period to enroll in MA or MA–PD plan. This also supports President Biden's April 5, 2022 *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,*[107] 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 health care providers.

This proposed change in the ICEP timeframe aligned with the SEP timeframe that we have established in § 422.62(b)(10), for individuals to enroll in an MA or MA–PD plan when their Medicare entitlement determination is made for a retroactive effective date, and the individual has not been provided the opportunity to elect an MA or MA–PD plan during their ICEP. It also aligned with the timeframe we have established in § 422.62(b)(26), effective January 1, 2024, for an individual to enroll in an MA plan when they enroll in Part A and/or Part B using an exceptional condition SEP, as described in §§ 406.27 and 407.23.

This final rule would extend the timeframe of an existing enrollment period, but we noted it would not result in a new or additional paperwork burden since MA organizations are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. All burden impacts of these provisions have already been accounted for under OMB control number 0938–1378 (CMS–10718). Similarly, we did not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: All commenters supported our proposed policy to extend the ICEP for those individuals who are first entitled to Part A and enrolled in Part B and did not enroll in Part A and B during their IEP. Many commenters stated this extended timeframe would provide beneficiaries more time to evaluate their options for coverage. Another commenter said this additional enrollment allowance will be welcome by many beneficiaries who are still learning and adjusting to the Medicare program. A commenter added that this additional time would allow beneficiaries to consider the benefits of MA enrollment, including care coordination services and the availability of supplemental benefits. A commenter added that expanding the opportunity for beneficiaries to choose the appropriate plan ensures that they will more likely be satisfied with their plan choice and coverage options. Another commenter added that this additional time will also provide Medicare Advantage Organizations (MAOs) with additional opportunity to further educate individuals on what options are available to them.

Response: We agree and thank the commenters for their support.

Comment: A commenter asked CMS to explain how the new proposed ICEP timeframe is different from the SEP that provides individuals with 2 months to elect a stand-alone Part D Plan or MA plan once their retiree or current employer group health plan ends.

Response: An SEP exists for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan (with or without drug coverage) or a Part D plan (§§ 422.62(b)(4) and 423.38(c)(11)). This SEP is only for use in accordance with

[107] *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/executive-order-on-continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage/.*

an individual's change in employer coverage and ends 2 months after the month the employer or union coverage ends. The ICEP is not limited for use based on the gain or loss of employer or union sponsored coverage. It is a universal election period available to all individuals to elect an MA plan (with or without prescription drug coverage) starting 3 months immediately before the individual's first entitlement to both Medicare Part A and Part B and will end, as proposed, the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B or the last day of the individual's Part B IEP, whichever is later.

Comment: Although they support our proposal to extend the timeframe for the ICEP, several commenters recommended alternate timeframes for the end of the ICEP. The commenters encouraged CMS to consider extending the proposed ICEP timeframe to end 3 full months after the month the individual is first entitled to Part A and enrolled in Part B. This timeframe would mirror the current IEP, wherein an individual would have a total of 7 months (prior to, at the time of, and after their first entitlement to Part A and enrollment in Part B) to consider their enrollment choice. The commenters stated that, due to the complex decision-making that must take place during these initial coverage situations, individuals newly eligible for Medicare would benefit greatly from additional time and that this timeframe would simplify policy since it would mirror the current IEP. A commenter suggested that CMS consider extending the ICEP timeframe to mirror the Medicare Advantage Open Enrollment Period (MA OEP), that is, to end on the last day of the third month that the individual is first entitled to Part A and enrolled in Part B, which would be a total of 6 months.

Response: We thank the commenters for their suggestions. We considered various ending dates when we proposed to extend the ICEP timeframe. As stated in the proposed rule, the proposed change in the ICEP timeframe aligns with the SEP timeframe that we established in § 422.62(b)(10) for individuals to enroll in an MA or MA–PD plan when their Medicare entitlement determination is made for a retroactive effective date and the individual has not been provided the opportunity to elect an MA or MA–PD plan during their ICEP. It also aligns with the timeframe we established in § 422.62(b)(26) for an individual to enroll in an MA or MA–PD plan when they enroll in Part A and/or Part B using an exceptional condition SEP which was recently codified in the April 2023 final rule (88 FR 22328).

The proposed timeframe to extend the ICEP will provide individuals a total of 5 months to consider how they want to receive their Medicare coverage. We believe this timeframe is adequate for beneficiaries to decide if they want to receive their coverage through Original Medicare or an MA plan and to select a plan that meets their needs. To note, individuals also have ample opportunities to change plans outside of the ICEP, including the MA OEP, the Annual Coordinated Election Period, or any SEP for which they are eligible.

Comment: Several commenters expressed support for the proposed changes to the ICEP timeframe, but provided feedback on areas that were not addressed in the proposed rule. A commenter stated that beneficiaries in traditional Medicare should have an opportunity to change stand-alone Part D plans during the first 3 months of the year—an option that is available to people who wish to change MA plans through the MA OEP. The commenter also stated that federal Medigap rights should be expanded to allow individuals to purchase such plans on at least an annual basis. Another commenter asked CMS to simplify the enrollment and plan selection processes—including by modernizing consumer tools, notifying people approaching Medicare eligibility about enrollment rules and timelines, and ensuring agency communications clearly explain the trade-offs between Original Medicare and MA.

Response: We thank the commenters for their support of the change to the ICEP timeframe, but we note that these recommendations are outside of the scope of this rulemaking.

After consideration of all public comments, we are finalizing our proposal to revise § 422.62(a)(1)(i) without modification.

Q. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

Medicare Advantage (MA) enrollees have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. The regulations for these reviews at the request of an MA enrollee are located at 42 CFR 422.624 and 422.626. Section 422.624 requires these providers of services to deliver a standardized written notice to the enrollee of the MA organization's decision to terminate the provider's services for the enrollee. This notice, called the Notice of Medicare Non-Coverage (NOMNC), must be furnished to the enrollee before services from the providers are terminated. The NOMNC informs enrollees of their right to a fast-track appeal of the termination of these provider services and how to appeal to the IRE. CMS currently contracts with certain Quality Improvement Organizations (QIOs) that have contracts under Title XI, Part B and section 1862(g) of the Act to perform as the IRE for these specific reviews. Specifically, the Beneficiary and Family Centered Care QIOs (BFCC QIOs) are the type of QIO that currently performs these reviews. There is a parallel appeal process in effect for Medicare beneficiaries in Original Medicare (42 CFR Part §§ 405.1200 and 405.1202).

Presently, if an MA enrollee misses the deadline to appeal as stated on the NOMNC, the appeal is considered untimely, and the enrollee loses their right to a fast-track appeal to the QIO. Enrollees may, instead, request an expedited reconsideration by their MA plan, as described in § 422.584. The QIO is unable to accept untimely requests from MA enrollees but does perform appeals for untimely requests from Medicare beneficiaries in Original Medicare as described at § 405.1202(b)(4).

Further, MA enrollees forfeit their right to appeal to the QIO if they leave a facility or otherwise end services from one of these providers before the termination date listed on the NOMNC, even if their appeal requests to the QIO are timely. (The MA enrollee retains the right to appeal to their MA plan in such cases because the decision to terminate the services is an appealable organization determination per § 422.566(b)(3).) Beneficiaries in Original Medicare retain their right to appeal to the QIO, regardless of whether they end services before the termination date on the NOMNC.

We proposed to modify the existing regulations regarding fast-track appeals for enrollees when they untimely request an appeal to the QIO, or still wish to appeal after they end services on or before the planned termination date. As noted in the proposed rule, these changes would bring the MA program further into alignment with Original Medicare regulations and procedures for the parallel appeals process. Finally, these changes were recommended by interested parties in comments to a previous rulemaking (CMS–4201–P, February 27, 2022).

Specifically, the changes would (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) allow enrollees the right to appeal the decision to terminate services after leaving a SNF or otherwise ending covered care before the planned termination date. The proposed changes are modeled after the parallel process in effect for Original Medicare at 42 CFR 405.1200 through 405.1202.

To implement these changes, we proposed to revise § 422.626(a)(2) to specify that if an enrollee makes an untimely request for a fast-track appeal, the QIO will accept the request and perform the appeal. We also specified that the IRE decision timeframe in § 422.626(d)(5) and the financial liability provision in § 422.626(b) would not apply.

Secondly, we proposed removing the provision at § 422.626(a)(3) that prevents enrollees from appealing to the QIO if they end their covered services on or before the date on their termination notice, even in instances of timely requests for fast-track appeals. Removal of this provision preserves the appeal rights of MA enrollees who receive a termination notice, regardless of whether they decide to leave a provider or stop receiving their services.

This proposed expedited coverage appeals process would afford enrollees in MA plans access to similar procedures for fast-track appeals as for beneficiaries in Original Medicare in the parallel process. Untimely enrollee fast-track appeals would be absorbed into the existing process for timely appeals at § 422.626, and thus, would not necessitate additional changes to the existing fast-track process. The burden on MA plans would be minimal and would only require that MA plans provide notices as required at § 422.626(d)(1) for these appeals. Further, MA plans would no longer have to perform the untimely appeals as currently required at § 422.626(a)(2). Beneficiary advocacy organizations, in comments to previous rulemakings on this topic, supported changes that would afford enrollees more time to appeal and afford access to IRE appeals even for untimely requests.

We noted that the burden of conducting these reviews is currently approved under OMB collection 0938–0953. The proposed changes would require that untimely fast-track appeals would be performed by the QIO, rather than the enrollee's health plan; thus, any burden related to this proposal would result in a shift in fast-track appeals from health plans to QIOs.

We received the following comments, and our responses follow.

Comment: We received numerous comments on our proposal to require the BFCC–QIO, instead of the plan, to review untimely fast-track appeals of a plan's decision to terminate services in an HHA, CORF, or SNF and to fully eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave a SNF or CORF. Nearly all interested parties commenting on this provision supported these policies. A commenter stated that permitting enrollees to maintain access to a BFCC–QIO review beyond this timeframe is important and, as noted in the proposed rule, provides parity with Original Medicare. Another commenter commended CMS for seeking uniform appeal rights between MA and Original Medicare and addressing access disparities, particularly in post-acute care.

Response: We appreciate the widespread support we received for this proposal and share the commenters' goal of parallel QIO appeals processes, whenever possible, for MA and Original Medicare. We intend to continue the current policy of having the BFCC–QIOs perform these appeals.

Comment: Several commenters suggested that CMS make parallel changes to § 422.622(a)(5), which pertains to late appeal requests for expedited appeals for inpatient hospital discharges. Additionally, a commenter wanted to extend the scope of the fast-track appeals process to include outpatient services.

Response: We appreciate these suggestions from the commenters and will take them into consideration for future rulemaking. We believe that such a change should be adopted only after notice and an opportunity for the public to comment on such a revision to the hospital discharge process.

Comment: A few commenters asked that we reflect these new policies in related beneficiary appeals notices as well as plan materials such as EOCs, manuals, and other guidance. Another commenter suggested that CMS engage in efforts to educate enrollees of their appeal rights.

Response: We thank the commenters for their suggestions related to necessary changes to notices and plan materials resulting from this provision. We will update manuals and other guidance as well as beneficiary materials pertaining to appeal rights, as appropriate. In addition, we will make necessary revisions to the standardized notice, required under § 422.624, which informs beneficiaries of their right to a fast-track appeal by an BFCC–QIO. This standardized notice, the NOMNC, is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB), and as such, any changes made to the NOMNC will be subject to public notice and comment.

Comment: A few commenters asked for clarification on the deadline to request an untimely appeal and whether the intent is for these MA provisions to precisely mirror procedures for Original Medicare. Another commenter recommended that CMS adopt a 60-day deadline for untimely enrollee appeals to plans.

Response: As finalized in this rule, per § 422.626(a)(2), a QIO will accept untimely requests for review of the termination of CORF, HHA or SNF services from enrollees. There is no deadline in this provision, and this is consistent with the parallel provision for Original Medicare at § 405.1204(b)(4). Our intent is to conform the QIO appeal processes for terminations of these provider services for Original Medicare and MA and to bring the MA appeals process in line with the parallel reviews for beneficiaries in Original Medicare. To that end, this provision, by design, mirrors the process for Original Medicare appeals of this type, set forth at § 405.1204(b)(4), rather than the process for enrollees set forth at § 422.584, which has a 60-day deadline to for an enrollee to file an appeal with the MA plan of an organization determination.

Comment: A commenter requested clarification on BFCC–QIO processing time for untimely requests. This commenter also asked if an enrollee could appeal to the plan if the BFCC–QIO decision is unfavorable. If so, the commenter requested clarification on the applicable processing timeframes.

Response: We appreciate the request for clarification on QIO processing timeframes and the interrelationship between QIO and plan appeals. Under the provisions we are finalizing at § 422.626(a)(2), a QIO will accept untimely requests from enrollees but the timeframes under (d)(5) of this section will not apply, as those timeframes pertain to timely requests. Consistent with the parallel regulations at § 405.1202(b)(4) for untimely Original Medicare appeals, the QIO will make its determination as soon as possible. We note that the provision we are finalizing in this rule has no effect on existing policy with respect to the MA plan appeals process set forth at §§ 422.582 and 422.584. As per current policy, an enrollee may appeal to the QIO and the

plan, but plan appeals deadlines continue as set forth at § 422.582(b).

Comment: A commenter was concerned about perceived implementation barriers health plans might encounter from these provisions. The commenter stated that there could be challenges with the availability of SNF beds and SNF readmissions for patients in rural areas should they request and receive a favorable BFCC–QIO appeal decision.

Response: We appreciate the commenter's concerns about perceived access issues particular to rural areas. However, as noted in the proposed rule, we expect only a very small increase in appeals to the overall existing appeals volume as a result of this provision. We also note that the acceptance of untimely appeals is a longstanding policy of the parallel appeals process for Original Medicare, with no known challenges regarding access particular to rural providers.

Comment: A commenter asked that we include language to state to which non-hospital providers these provisions would apply.

Response: As stated in the preamble, the relevant provisions for these reviews are found at §§ 422.624 and 422.626. Section 422.624(a)(1) specifies that providers included in this provision are skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. The untimely appeals affected by the provisions in this final rule are the reviews of the terminations of services from the providers specified at § 422.624(a)(1). Section 422.626, which we are amending in this final rule, establishes the fast appeals for an MA plan's decision to terminate the services specified in § 422.624. As the non-hospital provider types applicable to these reviews are already specified, we do not believe further regulatory revisions are necessary to address this comment.

Comment: A commenter expressed concern that the proposal will interfere with value based contracting relationships. The commenter indicated MA plans are familiar with value-based arrangements, supplemental benefits, and graduated care programs, and thus expressed concern with removing appeals to the plans from the appeal processes for terminations of CORF, HHA and SNF services. The commenter also raised concerns that adding the BFCC–QIO into the process for untimely fast track appeals adds another party and additional complexity to conversations requiring high levels of scrutiny and understanding of the needs of an enrollee. The commenter also maintained there could be a significant administrative burden created if providers encourage or ''coach'' enrollees to take a default position of appealing termination decisions. Finally, the commenter indicated these provisions could expose the patients to longer lengths of inappropriate care and significant personal liability.

Response: We thank the commenter for their perspective. However, we do not believe this provision will interfere with value-based contracting relationships or result in inappropriate care, nor do we anticipate any changes with respect to the providers' role, including creation of any incentives to improperly influence an enrollee's decision on whether to request a fast-track appeal. As we have stated, this provision solely addresses the allowance for untimely appeals by enrollees in the current, longstanding process for MA fast-track appeals of terminations of CORF, HHA and SNF services. These additional, untimely appeals will be processed under current appeals procedures. This process, currently applicable to timely fast-track appeals, already includes QIOs as the entity conducting these independent reviews. Finally, as stated in the proposed rule, we estimate a minimal increase of less than 3 percent in the total appeals volume for this existing appeals process. Thus, we expect no significant change in the administrative burden in any aspect of the process or any significant change to overall lengths of stay in the provider types covered by this provision.

Comment: We received a few comments pertaining to the denial of care by plans. A commenter requested that we take measures to ensure that enrollees receive care equivalent to beneficiaries in Original Medicare with a particular interest in post-acute care. A few commenters expressed concerns with plans' use of utilization management guidelines rather than appropriate Medicare coverage criteria. Another commenter recommended not allowing care to be terminated at all, but acknowledged this may not be possible within existing statutory or regulatory frameworks, and supported the enhancement of enrollee's rights, in the meantime.

Response: We thank the commenters for their thoughts but note that these issues are outside the scope of this proposal. At the same time, we do wish to acknowledge that many of the recommendations related to patient care and prior authorization processes have been recently addressed in other regulation issued by CMS. See ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,'' which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758) that established new requirements for MA organizations that will enhance the electronic exchange of health care data and streamline processes related to prior authorization while reducing overall payer and provider burden and ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.'' which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) that finalized regulatory changes clarifying when MA organizations may utilize prior authorization processes, the effect and duration of prior authorization approvals, and the circumstances under which MA organizations may utilize internal or proprietary coverage criteria.

Comment: A commenter expressed concern regarding overutilization of services (specifically reaching or exceeding the 100 days benefit limit for SNF stays) if this provision is finalized.

Response: We appreciate the concern of the commenter, but do not agree that finalizing this provision will result in the overutilization of services. First, if an enrollee requests an untimely appeal of the termination of SNF coverage and receives a favorable decision by the QIO, any resulting additional benefits days would demonstrate that the services meet medical necessity as well as coverage requirements. Second, favorable QIO decisions do not override any existing Part A SNF benefit limitations.

Comment: Two commenters requested clarification on plan and provider responsibilities for appeals affected by this provision. Specifically, the commenters asked for more information regarding whether health plans or providers are responsible for producing medical records for untimely appeals. The commenter also asked whether a plan would be responsible for days of

coverage, should the BFCC–QIO rule in favor of the enrollee in the appeal, and if this would also be true if the enrollee appeals after leaving a skilled nursing home.

Response: We note that plan and provider responsibilities for these untimely QIO appeals of terminations of CORF, HHA and SNF services will be the same as for timely appeals in the current process as set forth at §§ 422.624 through 422.626. Specifically, § 422.626(e)(3) states a plan is responsible for supplying all necessary medical records to the QIO, once the plan is notified of the appeal. Should plans wish to delegate this responsibility to contracted providers, that would be a contracting arrangement and outside the purview of CMS. However, MA plans remain ultimately responsible for compliance with this requirement. Plans' financial responsibilities will continue to be as set forth at § 422.626(b). Among other requirements, this section requires that coverage of provider services continues until the date and time designated on the NOMNC, unless the enrollee appeals and the IRE reverses the plan's decision. If the IRE reverses the plan's termination decision, coverage of provider services shall resume or apply in accordance with the QIO's decision, and the provider must provide the enrollee with a new notice consistent with § 422.626(b) when the enrollee is still present in the facility.

Comment: A commenter suggested that instruction was needed for situations where an untimely fast-track appeal request was incorrectly submitted to the MA plan, rather than to the BFCC–QIO.

Response: We appreciate the commenter's suggestion to revise plan level guidance related to this provision. Currently, Section 50.2.2 of the Parts C & D Enrollee Grievances, Organization/ Coverage Determinations, and Appeals Guidance [108] instructs plans to maintain a process to distinguish between misdirected requests that should go to the QIO and valid requests to the plan. We will update the guidance in this manual section to reflect that untimely requests intended for the QIO must be included in those appeals that are to be redirected to the QIO.

Comment: A commenter recommended additional language to protect provider contracts and that guidance to require such language be posted in facilities and included in admission documentation.

Response: We thank the commenter for their comment. However, without further specifics on which contracts and language to which the commenter is referring, we are unable to address these recommendations. We note that we will update the related standardized appeals notice and Notice of Medicare Non-Coverage (NOMNC) required under § 422.624 as well as other materials, as appropriate to reflect the changes adopted in this final rule In addition, § 422.504(i)(4) provides that MA organizations must ensure that their agreements with related, first tier, downstream entities, which include providers under contract with the MA organization to furnish services, clearly identify any delegated responsibilities. We anticipate that MA organizations will comply with these requirements to the extent that the changes we are finalizing to § 422.626 affect the scope of provider duties under their contracts with MA plans.

Comment: A commenter expressed concerns about whether the BFCC–QIOs could absorb the potential increase in appeals that may result from this provision. The commenter suggested that we assess the capacity of BFCC–QIOs prior to implementation of this provision.

Response: We appreciate the commenter's concerns. We do not anticipate an appreciable increase in the appeals volume as a result of this provision. Additionally, we plan to further assess and mitigate as possible and appropriate any workload impacts of transitioning these appeals prior to the implementation date.

Comment: A commenter expressed their perception that BFCC–QIOs uphold nearly all fast-track appeals. The commenter recommended that we publish BFCC–QIO appeals data and use these metrics for evaluating BFCC–QIO contracts.

Response: We thank the commenter for sharing their concerns and recommendations but note that these issues are outside the scope of this rulemaking.

After consideration of all public comments and for the reasons outlined in the proposed rule and our response to public comments, we are finalizing without modification our proposals to amend § 422.626(a)(2) and to remove § 422.626(a)(3).

R. Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514)

CMS has authority under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act to require MA organizations and Part D plan sponsors to provide CMS ''with such information . . . as the Secretary may find necessary and appropriate.'' CMS also has authority, in section 1856(b) of the Act, to establish standards to carry out the MA program.

Likewise, existing CMS regulations cover a broad range of topics and data to be submitted to CMS. Under these authorities, CMS established reporting requirements at §§ 422.516(a) (Validation of Part C reporting requirements) and 423.514(a) (Validation of Part D reporting requirements), respectively. Pursuant to §§ 422.516(a) and 423.514(a), each MA organization and Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report information to CMS at the times and in the manner that CMS requires. In addition, §§ 422.504(f)(2) and 423.505(f)(2) require MA organizations and Part D plan sponsors, respectively, to submit to CMS all information that is necessary for CMS ''to administer and evaluate'' the MA and Part D programs and to facilitate informed enrollment decisions by beneficiaries. Part D plan sponsors are also required to report all data elements included in all its drug claims by § 423.505(f)(3). Sections 422.504(f)(2), 422.516(a), 423.505(f)(2), and 423.514(a) each list general topics of information and data to be provided to CMS, including benefits, enrollee costs, quality and performance, cost of operations, information demonstrating that the plan is fiscally sound, patterns of utilization, information about beneficiary appeals, and information regarding actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

For many years, CMS has used this authority to collect retrospective information from MA organizations and Part D plan sponsors according to the Parts C and D Reporting Requirements that we issue each year, which can be accessed on CMS's website.[109] In addition to the data elements, reporting frequency and timelines, and levels of reporting found in the Reporting Requirements information collection documents, CMS also issues Technical Specifications, which supplement the Reporting Requirements and serve to further clarify data elements and outline CMS's planned data analyses. The reporting timelines and required levels

[108] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

[109] Part C Reporting Requirements are at *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/reportingrequirements* and Part D Reporting Requirements are at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxcontracting_reportingoversight.*

of reporting may vary by reporting section. While many of the current data elements are collected in aggregate at the contract level, such as grievances, enrollment/disenrollment, rewards and incentives, and payments to providers, the collection of more granular data is also supported by the regulations. CMS has the ability to collect more granular data, per the Part C and D Reporting Requirements as set forth in §§ 422.516(a) and 423.514(a), or to collect more timely data with greater frequency or closer in real-time than we have historically done. We proposed revisions to update §§ 422.516(a) and 423.514(a). Section 422.516 currently provides, ''Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information.'' We proposed to strike the term ''statistics,'' as well as the words ''and other,'' with the understanding that the broader term ''information'' which is already at § 422.516(a), includes statistics, Part C data, and information on plan administration. In a conforming proposal to amend § 423.514(a), we proposed to strike the term ''statistics'' and add ''information.'' CMS does not interpret the current regulations to limit data collection to statistical or aggregated data and we used the notice of proposed rulemaking as an opportunity to discuss our interpretation of these rules and amend the regulations consistent with our interpretation.

Additionally, we proposed to amend §§ 422.516(a)(2) and 423.514(a)(2) to make an affirmative change regarding CMS's collection of information related to what occurs from beginning to end when beneficiaries seek to get coverage from their Medicare health and drug plans for specific services. Both §§ 422.516(a)(2) and 423.514(a)(2) currently require plans to report ''[t]he patterns of utilization of services.'' We proposed to amend both sections to read, ''The procedures related to and utilization of its services and items'' to clarify that these regulations authorize reporting and data collection about MA organizations and Part D plan sponsor procedures related to coverage, utilization in the aggregate, and beneficiary-level utilization, including the steps beneficiaries may need to take to access covered benefits. Such information will ensure that CMS may better understand under what circumstances plans choose whether to provide or pay for a service or item.

CMS did not propose to change specific current data collection efforts through this rulemaking. While §§ 422.516(a) and 423.514(a) provide CMS extensive flexibility in the time and manner in which we can collect data from MA organizations and Part D plan sponsors, we will continue to address future standardized information collection of the Parts C and D reporting requirements, as necessary, through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process, which would provide advance notice to interested parties and provides both a 60 and 30 day public comment period on drafts of the proposed collection.

We do not believe the proposed changes to §§ 422.516(a) and 423.514(a) have either paperwork burden or impact on the Medicare Trust Fund at this time. These proposed changes allow CMS, in the future, to add new burden to plans in collection efforts; however, any such new burden associated with a new data collection would be estimated through the PRA process, as applicable.

We received the following comments, and our responses follow.

Comment: We received several comments in support of the reassertion of our authority to engage in new or more frequent data collection, including collection of more granular data from MA organizations and Part D plan sponsors. The majority of commenters expressed general support for our proposal to affirm CMS's authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements. We did not receive any comments objecting to the reassertion of authority to collect data that we included in the proposed rule.

Response: We appreciate the comments in support of our proposal.

Comment: In further support of the proposal, many commenters recommended CMS collect data elements for specific areas of interest, including data related to enrollee's cost-sharing for Part D medications, disease modification trends, multiple sclerosis diagnoses and enrollee demographics, plan referrals to specialists (*e.g.,* neurologists), End-Stage Renal Disease (ESRD) services, social determinants of health (*e.g.,* access to transportation, food insecurity, need for rental/utility assistance), plan use of prior authorization in specific settings, length of stays in post-acute care facilities, rehospitalization rates, qualifications of plan organization determination and appeal reviewers, plan use of algorithm and artificial intelligence when making coverage determinations, Medicaid coverage, pharmacy benefit managers, point-of-sale coverage decisions, service-level initial determinations, and initial determination denial rationale. Some commenters also requested we collect aggregate data elements that are already collected by CMS through the Parts C and D Reporting Requirements, including initial determination denials and appeal overturns made by the plan and Independent Review Entities.

Response: We thank the commenters for the data collection suggestions. We did not propose to implement changes to specific current data collection efforts in this rulemaking and would like to reiterate that any future information collection would be addressed through the OMB PRA process, as applicable, which would provide advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection.

Comment: Several commenters noted the positive benefit that robust data collection may generally have on strengthening CMS oversight of MA organizations and Part D plan sponsors, identifying and reducing potential gaps in health coverage policy, and ensuring enrollees have meaningful access to care. Some commenters suggested CMS incorporate collected data into plan audits and enforcement actions. A number of commentors also suggested CMS publish collected data on consumer-facing websites to improve transparency and plan accountability by allowing beneficiaries to compare plans' performance data.

Response: We appreciate the commenters' support and agree with the significance of CMS's role in overseeing MA organizations and Part D plan sponsors to ensure enrollees have continued access to care. We also agree the collection of more detailed standardized information from MA organizations and Part D plan sponsors is a necessary step in improving transparency and data in the MA and Part D programs. We will take these comments related to increasing oversight and transparency of the MA and Part D programs into consideration when developing future processes related to the public sharing of collected plan data.

Comment: A few commenters recommended that CMS consider a further revision to the proposed language in § 422.516(a), specifically the term ''doctor-patient relationship.'' A commenter noted that health care is increasingly delivered by a wider range of roles than just physicians and recommended that we replace the term

''doctor-patient'' with ''clinician-patient'' to better reflect the need for confidentiality between patients and their entire healthcare team.

Response: We appreciate the commenters' suggestion to modify the regulation text in § 422.516(a) to reflect the diverse team of health care professionals who provide care to MA enrollees. While we did not specifically propose to replace the term ''doctor'' with a more inclusive term in the introductory text at § 422.516(a), we agree with this suggestion. Accordingly, we are modifying § 422.516(a) in this final rule and replacing the term ''doctor-patient relationship'' with ''provider-patient relationship.'' Although commenters suggested the term ''doctor'' be replaced with ''clinician,'' the term ''provider'' is defined in § 422.2 and used throughout 42 CFR part 422 when describing health care professionals and entities that furnish health care services to MA enrollees. For example, the regulation text at § 422.200 explains, in part, that the provisions in Subpart E govern MA organizations' relationships with providers by setting forth ''requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans.'' Therefore, replacing ''doctor-patient'' with ''provider-patient'' in § 422.516(a) will enhance clarity and consistency across regulation text in Part 422.

Comment: One commenter suggested that for future data collection efforts CMS utilize notice-and-comment rulemaking instead of the PRA process to provide stakeholders a greater opportunity to comment on the future proposal.

Response: We appreciate the commenter's concern that stakeholders should have opportunity to comment on changes to the MA and Part D reporting requirements. When applicable, CMS uses notice-and-comment rulemaking to solicit public comments on proposed information collection requirements. CMS must also comply with the implementing regulations of the PRA at 5 CFR 1320.10 (clearance of collections of information, other than those contained in proposed rules or in current rules), 1320.11 (clearance of collections of information in proposed rules), and 1320.12 (clearance of collections of information in current rules). CMS's compliance with the PRA, when required, allows interested parties to review and comment on future information collection request changes via two required public notice and comment periods; that is, the 60-day and 30-day notice and comment periods.

While 42 CFR 422.516(a) and 423.514(a) [110] provide CMS extensive flexibility in the time and manner in which we can require reporting by (and/or collect data from) MA organizations and Part D plan sponsors, as explained above, CMS must adhere to the implementing regulations of the OMB PRA process, when required, including circumstances when CMS collects data in a standardized format from 10 or more respondents. For any future information collection applicable to all MA organizations and Part D plan sponsors or groups larger than 9, we will, as necessary, use the OMB PRA process when proposing future Parts C and D reporting requirement changes. The PRA process provides the opportunity for interested parties to have notice of and comment on future data collection changes. As we stated in our proposal, the OMB PRA process provides advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection. Therefore, we believe the PRA process is appropriate and sufficient to use when establishing any future data collection subject to its terms.

Comment: While indicating overall support for CMS's position, a commenter requested more clarification on the purpose of increasing CMS's data collection from MA organizations and Part D plan sponsors and requested CMS work with the industry to minimize and reduce reporting burdens. Specifically, the commenter suggested CMS establish guidelines for its proposal and implement the Part C and D plan reporting requirements before proposing new collections.

Response: As we explained in the proposed rule, an increase in detailed data collection would increase transparency as well as CMS's access to data in the MA and Part D programs. The data currently acquired through the Parts C and D reporting requirements are often used for monitoring an MA organization's or Part D plan sponsor's continued compliance with MA and Part D requirements as well as evaluating the success of these programs. At times, we may use an outlier analysis to determine a plan or sponsor's performance relative to industry standards established by the performance of all other organizations and sponsors. *See* §§ 422.504(m) and 423.505(n). Increasing the quality of the data CMS has to support these practices would enhance our ongoing monitoring and enforcement responsibility for the MA and Part D programs. Additionally, a comprehensive, high-quality database of MA and Part D programmatic data will promote more program transparency and assist our efforts to identify and close potential gaps in access to care for Medicare beneficiaries enrolled in these programs.

When creating any new data collection initiative, we will consider and account for the impact the initiative would have on plans and sponsoring organizations and will make an effort to avoid creating excessive burdens, both when necessary to comply with the PRA and as part of our administration of the programs even if the PRA is not applicable. Further, in developing additional meaningful future data collection changes, we are committed to obtaining input from all interested parties as necessary. As we stated in our proposal, the OMB PRA process provides advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection. Interested parties will have an opportunity to comment on specific guidelines for reporting requirements under consideration.

After consideration of all public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed, with a minor modification at § 422.516(a) to replace the term ''doctor-patient relationship'' with ''provider-patient relationship''.

S. Amendments To Establish Consistency in Part C and Part D Timeframes for Filing an Appeal Based on Receipt of the Written Decision (§§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600)

We proposed to amend the Parts C and D regulations at §§ 422.582(b), 422.584(b), 422.633(d)(1), 423.582(b), 423.584(b) and 423.600(a) with respect to how long an enrollee has to file an appeal with a plan or the Part D Independent Review Entity (IRE). These amendments were proposed to ensure consistency with the regulations at §§ 422.602(b)(2), 423.2002(d), 422.608, and 423.2102(a)(3), applicable to Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) reviews. These ALJ and Council regulations state or cross-reference the Medicare FFS regulations at 42 CFR part 405 that prescribe that the date of

[110] CMS also possesses considerable authority to collect data and other specific information from MA organizations and Part D plan sponsors through §§ 422.504(f) and 423.505(f).

receipt of the notice of decision or dismissal is presumed to be 5 calendar days after the date of the notice unless there is evidence to the contrary. We also proposed that these changes apply to integrated organization determinations and reconsiderations. In addition, because cost plans are required to comply with the MA appeal regulations pursuant to §§ 417.600 and 417.840, these proposed changes will also apply to cost plan appeals.

Pursuant to our authority under section 1856(b) and 1860D–12 of the Act to adopt standards to carry out the Part C and Part D programs, and in order to implement sections 1852(g)(2) and 1860D–4(g) and (h) of the Act regarding coverage decisions and appeals, CMS established procedures and minimum standards for an enrollee to file an appeal regarding benefits with an MA organization, Part D plan sponsor, and IREs. These requirements are codified in regulation at 42 CFR parts 422 and 423, subpart M. See also section 1876(c)(5) of the Act regarding cost plans' obligations to have appeal processes.

Specifically, section 1852(g)(2)(A) of the Act requires that an MA organization shall provide for reconsideration of a determination upon request by the enrollee involved. The reconsideration shall be made not later than 60 days after the date of the receipt of the request for reconsideration. Section 1860D–4(g)(1) of the Act requires that a Part D plan sponsor shall meet the requirements of paragraph (2)(A) of section 1852(g) with respect to providing for reconsideration of a determination upon request by the enrollee involved.

While section 1852 of the Act does not specify the timeframe in which an enrollee must request an appeal of an unfavorable organization determination, integrated organization determination or coverage determination, the timeframe for filing an appeal in the Part C and Part D programs is established in regulations. Sections 422.582(b), 422.633(d)(1), and 423.582(b) state that an appeal must be filed within 60 calendar days from the date of the notice issued as a result of the organization determination, integrated organization determination, coverage determination, or at-risk determination. Plans are permitted to extend this filing deadline for good cause.

As noted in the proposed rule, we continue to believe that a 60 calendar day filing timeframe strikes an appropriate balance between due process rights and the goal of administrative finality in the administrative appeals process. However, to establish consistency with the regulations applicable to ALJ and Council reviews with respect to receipt of the notice of decision or dismissal and how that relates to the timeframe for requesting an appeal, we proposed to account for a presumption that it will generally take 5 calendar days for a notice to be received by an enrollee or other appropriate party. Therefore, we proposed to revise §§ 422.582(b), 422.633(d)(1)(i), 423.582(b), and 423.600(a) to state that a request for a Part C reconsideration, Part D redetermination, Part D at-risk redeterminations and Part D IRE reconsiderations must be filed within 60 calendar days after receipt of the written determination notice. We also proposed to add new §§ 422.582(b)(1), 422.633(d)(1)(i), and 423.582(b)(1), to provide that the date of receipt of the organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be 5 calendar days after the date of the written organization determination, integrated organization determination, coverage determination or at-risk determination, unless there is evidence to the contrary. Based on CMS's experience with audits and other similar review of plan documents, we realized that it was standard practice that the date of the written decision notice is the date the plan sends the notice. The presumption that the notice is received 5 calendar days after the date of the decision is a long-standing policy with respect to IRE appeals and has been codified in regulation at §§ 422.602(b)(2), 423.2002(d), and 423.2102(a)(3) regarding hearings before an ALJ and Council; further, § 422.608 regarding MA appeals to the Medicare Appeals Council provides that the regulations under part 405 regarding Council review apply to such MA appeals, which would include the provision at § 405.1102(a)(2) that applies the same 5 calendar day rule. To ensure consistency throughout the administrative appeals process, we proposed to adopt this approach for plan and Part D IRE appeals in §§ 422.582(b), 422.633(d)(1), 423.582(b), 423.584 and 423.600(a).

In addition to the aforementioned proposals related to when an organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be received by an enrollee of other appropriate party, we also proposed adding language to §§ 422.582, 422.633, 423.582 and 423.600(a) that specifies when an appeal is considered filed with a plan and the Part D IRE. Specifically, we proposed to add new §§ 422.582(b)(2), 422.633(d)(1)(ii), 423.582(b)(2) and 423.600(a) to provide that for purposes of meeting the 60 calendar day filing deadline, the appeal request is considered filed on the date it is received by the plan, plan-delegated entity or Part D IRE specified in the written organization determination, integrated organization determination, coverage determination, at-risk determination, or redetermination. As stated in the proposed rule, inclusion of when a request is considered filed would codify what currently exists in CMS's sub-regulatory guidance and the Part D IRE procedures manual. CMS's sub-regulatory guidance indicates that a standard request is considered filed when any unit in the plan or delegated entity receives the request. An expedited request is considered filed when it is received by the department responsible for processing it. Pursuant to existing manual guidance, plan material should clearly state where requests should be sent, and plan policy and procedures should clearly indicate how to route requests that are received in an incorrect location to the correct location as expeditiously as possible.

These proposed revisions related to when a notice is presumed to have been received would ensure that the time to request an appeal is not truncated by the time it takes for a coverage decision notice to reach an enrollee by mail or other delivery method. We noted that if the proposals were finalized, corresponding changes would be made to the Part C and Part D standardized denial notices so that enrollees are accurately informed of the timeframe for requesting an appeal.

We also proposed clarifications to §§ 422.584(b) and 423.584(b) to explicitly state the timeframe in which an enrollee must file an expedited plan appeal for it to be timely. The current text of §§ 422.584 and 423.584 does not include the 60 calendar day timeframe for filing an expedited appeal request, but as noted in the proposed rule, CMS manual guidance for Part C and Part D appeals has long reflected this 60 calendar day timeframe. We also noted that this timeframe for filing an appeal is consistent with the current regulations at §§ 422.582(b) and 423.582(b) for filing a request for a standard appeal. Neither sections 1852 and 1860D–4 of the Act, nor §§ 422.584 and 423.584 specify the timeframe in which an enrollee must request an expedited appeal of an unfavorable organization determination, coverage determination or at-risk determination in the Part C and Part D programs. This provision would codify existing

guidance. We are certain that plans already comply as this long-standing policy is reflected in CMS's sub-regulatory guidance [111] and standardized denial notices [112] that explain an enrollee's right to appeal. Additionally, we had not received any complaints on this matter. In proposing new §§ 422.584(b)(3) and (4) and 423.584(b)(3) and (4), we also proposed to add the procedure and timeframe for filing expedited organization determinations and coverage determinations consistent with proposed requirements at §§ 422.582(b)(1) and (2) and 423.582(b)(1) and (2).

If finalized, we believe these proposals will enhance consistency in the administrative appeals process and provide greater clarity on the timeframe for requesting an appeal and when an appeal request is considered received by the plan. Theoretically, the proposed amendments may result in a small increase in the number of appeals from allowing 65 versus 60 days to appeal an organization determination, integrated organization determination, coverage determination or at-risk determination. However, based on the low level of dismissals at the plan level due to untimely filing, we believe most enrollees who wish to appeal a denial do so immediately, thereby mitigating the impact of 5 additional days for a plan to accept an appeal request if this proposal is finalized. Consequently, we do not believe there is an impact to the Medicare Trust Fund. We solicited interested party input on the accuracy of this assumption.

We received the following comments, and our responses follow.

Comment: We received several comments in support of extending the current 60-day timeframe to file an appeal with an MA or Part D plan to include 5 additional calendar days as proof of receipt of the written determination notice believing that it expanded beneficiary access to the appeals process. Commenters appreciated that the additional time period would also apply to expedited appeal requests, expedited organization determinations, and coverage determinations, while a few of the commenters noted that the proposal was consistent with appeals timeframes in Social Security, SSI, and Medicare more generally, and provides needed clarity for enrollees and their representatives. A few commenters also expressed support and stated the proposal reflected the reality of slower post office delivery times in recent years, as well extra time needed to forward mail for individuals who have changed their addresses.

Response: We appreciate the comments in support of our proposal.

Comment: A commenter stated agreement with establishing consistency in Part C and Part D appeals timeframes, but suggested that instead of specifying that an appeal request be filed within in 60 calendar days after receipt of the written determination notice, CMS should instead require that appeal requests be filed within in 65 calendar days of the letter date.

Response: We thank the commenter for this recommendation; however, we decline to revise our proposal because CMS proposed these amendments to ensure consistency with the regulations at §§ 422.602(b)(2), 423.2002(d), 422.608, and 423.2102(a)(3), applicable to Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) reviews, that either state or cross-reference the Medicare FFS regulations at 42 CFR part 405 that prescribe that the date of receipt of the notice of decision or dismissal is presumed to be 5 calendar days after the date of the notice, unless there is evidence to the contrary. The commenters recommendation would not accomplish this consistency.

After consideration of the public comments, and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revisions to §§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600 as proposed.

T. Authorized Representatives for Parts C/D Elections (§§ 422.60 and 423.32)

Section 1851(c)(1) of the Act gives the Secretary the authority to establish a process through which MA elections, that is, enrollments and disenrollments, are made and changed. This authority includes establishing the form and manner in which elections are made. Section 1860D–1(b)(1)(A) of the Act gives the Secretary the authority to establish a process for enrollment, disenrollment, termination, and change of enrollments in Part D prescription drug plans. Likewise, section 1860D–1(b)(1)(B)(ii) of the Act directs CMS to use rules similar to those established in the MA context pursuant to 1851(c) for purposes of establishing rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan.

Consistent with these sections of the Act, Parts C and D regulations set forth our election processes under §§ 422.60 and 423.32. These enrollment processes require that Part C/D eligible individuals wishing to make an election must file an appropriate enrollment form, or other approved mechanism, with the plan. The regulations also provide information for plans on the process for accepting election requests, notice that must be provided, and other ways in which the plan may receive an election on behalf of the beneficiary.

Though the term ''authorized representative'' is not used in the context of the statutory provisions within the Act governing MA and Part D enrollment and eligibility (*e.g.,* sections 1851 and 1860D–1), ''authorized representative''—and other similar terms—are used in other contexts throughout the Act. Section 1866(f)(3) of the Act defines the term ''advance directive,'' deferring to applicable state law to recognize written instructions such as a living will or durable power of attorney for health care. Section 1862(b)(2)(B)(vii)(IV) of the Act recognizes that an individual may be represented by an ''authorized representative'' in secondary payer disputes. Section 1864(a) of the Act allows a patient's ''legal representative'' to stand in the place of the patient and give consent regarding use of the patient's medical records.

In the June 1998 interim final rule that first established the M+C program, now the MA program (63 FR 34985), we acknowledged in Part C enrollment regulations at § 422.60(c) that there are situations where an individual may assist a beneficiary in completing an enrollment request and required the individual to indicate their relationship to the beneficiary. In the Medicare Program; Medicare Prescription Drug Benefit final rule which appeared in the **Federal Register** on January 28, 2005, (70 FR 4193), we first recognized in § 423.32(b)(i) that an authorized representative may assist a beneficiary in completing an enrollment request, and required authorized representatives to indicate that they provided assistance. In response to public comments about the term ''authorized representative'' in that rule, we indicated that CMS would recognize and rely on State laws that authorize a person to effect an enrollment on behalf of a Medicare beneficiary for purposes of this provision (42 FR 4204). We also stated that the authorized representative would constitute the ''individual'' for purposes of making the enrollment or disenrollment request.

[111] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

[112] *https://www.cms.gov/medicare/medicare-general-information/bni/madenialnotices.*

Historically, we have provided the definition and policies related to authorized representatives in our sub-regulatory manuals.[113] We proposed in the November 2023 proposed rule to add new paragraphs §§ 422.60(h) and 423.32(h) to codify our longstanding guidance on authorized representatives making Parts C and D elections on behalf of beneficiaries.

Current regulation in § 423.32(b)(i) acknowledges that an ''authorized representative'' may assist a beneficiary in completing an enrollment form, but it does not define who an ''authorized representative'' is. A similar term, ''representative,'' is currently defined under §§ 422.561 and 423.560; however, that definition is used only in the appeals context and applies only to subpart M of the MA and Part D regulations. Therefore, we proposed to define the term ''authorized representative'' for subpart B (eligibility, election, and enrollment).

Our proposal deferred to the law of the state in which the beneficiary resides to determine who is a legal representative. Deference to state law on these matters is consistent with other similar practices within CMS, including in the MA appeals definition of ''representative'' (§ 422.561) and Medicaid's definition of ''authorized representative'' (§§ 435.923; 438.402), as well as in the HIPAA Privacy Rule description of ''personal representative'' (45 CFR 164.502(g)).

For those with state legal authority to act and make health care decisions on behalf of a beneficiary, we proposed to codify at paragraph (h)(1) of § 422.60 and (h)(1) of § 423.32 that authorized representatives will constitute the ''beneficiary'' or the ''enrollee'' for the purposes of making an election, meaning that CMS, MA organizations, and Part D sponsors will consider the authorized representative to be the beneficiary/enrollee during the election process. Any mention of beneficiary/enrollee in our enrollment and eligibility regulations would be considered to also include ''authorized representative,'' where applicable. Our proposal at paragraph (h)(2) of § 422.60 and (h)(2) of § 423.32 clarified that authorized representatives under state law may include court-appointed legal guardians, durable powers of attorney for health care decisions and state surrogate consent laws as examples of those state law concepts that allow the authorized representative to make health care decisions on behalf of the individual. This is not a complete list; we would defer to applicable state law granting authority to act and make health care decisions on behalf of the beneficiary.

Codifying this longstanding guidance provides plans, beneficiaries and their caregivers, and other interested parties clarity and transparency on the requirements when those purporting to be the representatives of the beneficiary attempt to make election decisions on their behalf. We have not received negative public feedback on this longstanding policy. However, we have recently answered questions on plan procedures when dealing with authorized representatives. We proposed to codify this longstanding guidance in order to clarify our policy regarding the role of authorized representatives in the MA and Part D enrollment process, including the applicability of state law in this context.

This proposal codifies longstanding MA and Part D sub-regulatory guidance. Based on questions from plans and beneficiaries related to current guidance, we concluded that the guidance had been previously implemented and is currently being followed by plans. Therefore, we concluded there was no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there would also be no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141).

We received the following comments, and our responses follow.

Comment: Several commenters expressed general support for this proposal, with one commenter noting that the term ''authorized representative'' can be ambiguous and, thus, it was good for CMS to codify the existing policy.

Response: We appreciate the comments in support of our proposal.

Comment: One commenter requested that CMS establish a form, outside of state law requirements, that individuals can use to appoint an authorized representative to act on their behalf for MA/Part D enrollment purposes.

Response: We thank the commenter for their proposal. We decline to revise our proposal because it is CMS's standard practice to defer to state law on similar matters of legally authorized representation. We believe that compliance with state law requirements for establishing authorized representation serves as an important form of beneficiary protection. We believe that states are better positioned to determine these requirements and resolve any disputes over representative appointment and scope.

Comment: One commenter suggested the removal of ''as the law of the State in which the beneficiary resides may allow,'' from our proposed regulatory text. The commenter was concerned that, as proposed, the regulatory text required state law to specifically address the appointment of a representative for Medicare enrollment purposes. The commenter also requested clarification on the difference between an authorized representative and those who provide information during, or otherwise assist the individual in, the enrollment process.

Response: We disagree with this interpretation. As stated above, we defer to applicable state law granting a representative the authority to act and make health care decisions on behalf of the beneficiary. States would not need to specifically address the power to make Medicare enrollment decisions on behalf of an individual. Authorized representatives may include court-appointed legal guardians, persons having durable powers of attorney, or individuals authorized to make health care decisions under state surrogate consent agreements, provided that the specific state law mechanism for establishing legal representation would allow the representative to make health care decisions on the individual's behalf.

We also clarify that assisting a beneficiary in the enrollment process is different from representing that beneficiary in a legal capacity. For example, a family member might help an individual read and fill out an enrollment application, but they are not completing the application on behalf of the individual. Assisting a family member is different from attesting that they are acting on their behalf as an authorized representative. If an individual is merely receiving assistance with the application, they would still complete and sign their own application. Whereas an authorized representative provides their signature and an attestation that they are authorized by law to act on the individual's behalf.

Comment: Several commenters requested that ''authorized representatives'' be excluded from the 48-hour waiting period between a Scope of Appointment and a personal

[113] This guidance can be found in Chapter 2, Sections 10 and 40.2.1 of the Medicare Managed Care Manual and Chapter 3, Sections 10 and 40.2.1 of the Prescription Drug Benefit Manual.

marketing appointment with an agent/broker.

Response: We thank the commenters for this recommendation, but these requests are related to existing marketing regulations and are, thus, outside the scope of the proposal.

After consideration of all public comments and for the reasons discussed here and in the proposed rule, we are finalizing our proposal with a technical change to add the language as new paragraphs §§ 422.60(i) and 423.32(j) instead of §§ 422.60(h) and 423.32(h).

U. Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§ 422.62(a)(4))

Section 1851(e) of the Act establishes the coverage election periods for making or changing elections in the M+C, later known as MA, program. Section 501(b) of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) amended Section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. CMS published a final rule with comment period (65 FR 40317) in June 2000 implementing section 1851(e)(2)(D) by establishing a new continuous open enrollment period for institutionalized individuals (OEPI) at then § 422.62(a)(6). In subsequent rulemaking (83 FR 16722), the OEPI regulations were further updated to reflect conforming changes related to implementation of Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) (70 FR 4717) and to redesignate this provision from § 422.62(a)(6) to (a)(4).

As noted above, the OEPI is continuous. Individuals may use the OEPI to enroll in, change, or disenroll from a plan. Individuals are eligible for the OEPI if they move into, reside in, or move out of an institution. Longstanding sub-regulatory guidance has stated that the OEPI ends 2 months after an individual moves out of an institution, but this has not been articulated in regulations.[114]

To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, we proposed in the November 2023 proposed rule to codify current sub-regulatory guidance that defines when the OEPI ends. Specifically, we proposed to codify at new subparagraph § 422.62(a)(4)(ii) that the OEPI ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of ''institutionalized'' at § 422.2.

This proposal defined when the OEPI ends and would not result in a new or additional paperwork burden since MA organizations are currently implementing the policy related to the OEPI end date as part of existing enrollment processes. All burden impacts related to an applicant's eligibility for an election period have already been accounted for under OMB control number 0938–0753 (CMS–R–267). Similarly, we stated in the proposed rule that we did not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: A commenter supported the proposal to codify the definition of when the OEPI ends.

Response: We thank the commenter for the support.

Comment: A commenter supported the proposal and encouraged CMS to further clarify that the OEPI also permits institutionalized individuals to enroll in a special needs plan (SNP) or Program of All-Inclusive Care for the Elderly (PACE) plan, in addition to an MA plan or Original Medicare.

Response: We appreciate the feedback and acknowledge that the OEPI allows institutionalized individuals to enroll in an MA plan, an SNP (which is a type of MA plan), or discontinue enrollment in an MA plan and enroll in Original Medicare. PACE is addressed under separate regulations and we note that individuals enrolling in the PACE program do not require an election period.

Comment: A commenter suggested that we include institutionalized-equivalent for purposes of OEPI.

Response: We appreciate the feedback but note that the proposed change pertained to the period of time in which an individual is eligible for the OEPI and able to make an election, not to the election period eligibility criteria. As such, this recommendation is outside of the scope of the proposed rulemaking.

After consideration of all public comments and for the reasons described here and in the November 2023 proposed rule, we are finalizing our proposal to amend § 422.62(a)(4) without modification.

V. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§ 422.68 and 423.40)

Section 1851(f) of the Act establishes the effective dates of elections and changes of elections for MA plans. In the June 1998 interim final rule, we specified the effective dates for elections and changes of elections of M+C (now MA) plan coverage made during various specified enrollment periods (63 FR 34968). The effective date requirements for the initial coverage election period (ICEP), annual election period (AEP), MA open enrollment period (MA–OEP), open enrollment period for institutionalized individuals (OEPI), and special election periods (SEP) are codified in regulation at § 422.68. For Part D plans, section 1860D–1(b)(1)(B)(iv) of the Act directs us to establish similar rules for effective dates of elections and changes of elections to those provided under the MA program statute at section 1851(f). In the January 2005 Part D final rule, we specified the effective dates for elections and changes of elections of Part D coverage made during various specified enrollment periods (70 FR 4193). The effective date requirements for the initial enrollment period (IEP) for Part D, AEP, and SEPs are codified in regulation at § 423.40.

Existing regulations at §§ 422.68 and 423.40 do not address what the MA organization or Part D plan sponsor should do when a beneficiary is eligible for more than one election period, thus resulting in more than one possible effective date for their election choice. For example, the beneficiary is eligible to make a change in their election choice during the MA–OEP, but they are also eligible for an SEP due to changes in the individual's circumstances. Current sub-regulatory guidance provides that the MA organization or Part D plan sponsor determine the proper effective date based on the election period for which the beneficiary is eligible before the enrollment or disenrollment may be transmitted to CMS.[115] Because the election period determines the effective date of the election in most instances, with the exception of some SEPs or when election periods overlap, beneficiaries may not request their election effective date. The MA organization or Part D plan sponsor determines the effective date once the election period is identified. If a beneficiary is eligible for more than one election period, which results in more than one possible effective date, CMS's sub-regulatory guidance[116] directs the

[114] This guidance can be found in Chapter 2, Section 30.3 of the Medicare Managed Care Manual.

[115] This guidance can be found in Chapter 2, Section 30.6 and 30.7 of the Medicare Managed Care Manual and Chapter 3, Section 30.4 and 30.5 of the Prescription Drug Benefit Manual.

[116] This guidance can be found in Chapter 2, Section 30.6 of the Medicare Managed Care Manual

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MA organization or Part D plan sponsor to allow the beneficiary to choose the election period that results in the desired effective date. To determine the beneficiary's choice of election period, MA organizations and Part D plan sponsors are instructed to attempt to contact the beneficiary, and to document their attempt(s). However, sub-regulatory guidance [117] states that this does not apply to beneficiary requests for enrollment into an employer or union group health plan (EGHP) using the group enrollment mechanism. Beneficiaries who make an election via the employer or union election process will be assigned an effective date according to the SEP EGHP, unless the beneficiary requests a different effective date that is allowed by one of the other election periods for which they are eligible.

Because a beneficiary must be entitled to Medicare Part A and enrolled in Medicare Part B in order to be eligible to receive coverage under an MA or MA–PD plan, CMS's sub-regulatory guidance [118] explains that if one of the election periods for which the beneficiary is eligible is the ICEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and enrollment in Part B. Likewise, because a beneficiary must be entitled to Part A or enrolled in Part B in order to be eligible for coverage under a Part D plan, sub-regulatory guidance explains that if one of the election periods for which the beneficiary is eligible is the Part D IEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and/or enrollment in Part B.[119]

Furthermore, sub-regulatory guidance [120] provides that if a beneficiary is eligible for more than one election period and does not choose which election period to use, and the MA organization or Part D plan sponsor is unable to contact the beneficiary, the MA organization or Part D plan sponsor assigns an election period for the beneficiary using the following ranking of election periods (1 = Highest, 5 = Lowest): (1) ICEP/Part D IEP, (2) MA–OEP, (3) SEP, (4) AEP, and (5) OEPI. The election period with the highest rank generally determines the effective date of enrollment. In addition, if an MA organization or Part D sponsor receives a disenrollment request when more than one election period applies, the plan is instructed to allow the beneficiary to choose which election period to use. If the beneficiary does not make a choice, then the plan is directed to assign the election period that results in the earliest disenrollment.

To provide transparency and stability about the MA and Part D program for plans, beneficiaries, and other interested parties, we proposed at new §§ 422.68(g) and 423.40(f) that if the MA organization or Part D plan sponsor receives an enrollment or disenrollment request, determines the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date, the MA organization or Part D plan sponsor must allow the beneficiary to choose the election period that results in the desired effective date. We also proposed at §§ 422.68(g)(1) and 423.40(f)(1) that the MA organization or Part D plan sponsor must attempt to contact the beneficiary and must document its attempt(s) to determine the beneficiary's choice. The plan may contact the beneficiary by phone, in writing, or any other communication mechanism. Plans would annotate the outcome of the contact(s) and retain the record as part of the individual's enrollment or disenrollment request. In addition, we proposed at §§ 422.68(g)(2) and 423.40(f)(2) to require that the MA organization or Part D plan sponsor must use the proposed ranking of election periods to assign an election period if the beneficiary does not make a choice. With the exception of the SEP EGHP noted earlier, if a beneficiary is simultaneously eligible for more than one SEP and they do not make a choice, and the MA organization or PDP sponsor is unable to obtain the beneficiary's desired enrollment effective date, the MA organization or PDP sponsor should assign the SEP that results in an effective date of the first of the month after the enrollment request is received by the plan. Finally, we proposed at §§ 422.68(g)(3) and 423.40(f)(3) to require that if the MA organization or Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, they must assign an election period that results in the earliest disenrollment.

This proposal represented the codification of longstanding MA and Part D sub-regulatory guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current guidance, we concluded that the guidance has been previously implemented and is currently being followed by plans. We concluded that there was no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there was also no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control number 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We received the following comments, and our responses follow.

Comment: Commenters were generally supportive of the proposal as written, with some commenters noting that it reflects current practices and prioritizes beneficiary preference.

Response: We thank the commenters for the support.

Comment: A commenter supported the proposal but suggested that CMS require plans to exhaust all available communication methods if the beneficiary does not respond to plan attempts to reach them.

Response: We appreciate the suggestion. However, we believe the parameters of the proposal to require the plan to attempt to contact the individual to indicate a desired effective date is sufficient. We encourage plans to attempt to contact individuals using all feasible communication methods including by phone, in writing, or another preferred method.

Comment: Several commenters suggested updating Medicare.gov to allow individuals to indicate their desired effective date during online enrollments, which would alleviate plan burden in needing to contact individuals who are eligible for more than one election period. One of the commenters added as an example that an individual may end up overlapping their EGHP coverage with Medicare coverage for a period of time if they do not understand the different enrollment timeframes or which SEP applies to their situation.

Response: We appreciate the commenters' feedback. We will consider future updates to Medicare.gov that would enable individuals to indicate their preferred effective date or provide explanations that help individuals better understand possible effective dates or which SEP timeframes apply to their situation.

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and Chapter 3, Section 30.4 of the Prescription Drug Benefit Manual.

[117] This guidance can be found in Chapter 2, Section 30.6 of the Medicare Managed Care Manual and Chapter 3, Section 30.4 of the Prescription Drug Benefit Manual.

[118] This guidance on effective dates of elections is currently outlined in section 30.6 of Chapter 2 of the Medicare Managed Care Manual.

[119] This guidance on effective dates of elections is currently outlined in section 30.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

[120] This guidance can be found in sections 30.6 and 30.7 of Chapter 2 of the Medicare Managed Care Manual and sections 30.4 and 30.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A commenter suggested that the individual should be asked by the plan at the time of their enrollment when they want their plan coverage to begin. The commenter added that if an individual does not select their desired effective date when they contact the plan to enroll, CMS should require the plan to space out the three-attempt contact requirement.

Response: We appreciate the feedback. If an individual is enrolling with the plan in person or by phone, we encourage the plan to ask the individual to indicate their preferred effective date. The proposal and sub-regulatory guidance do not specify that plans need to make three attempts to contact the individual if they do not indicate their preferred effective date. However, plans are strongly encouraged to make multiple contact attempts to request additional information from individuals before assigning an effective date.

Comment: A commenter requested additional information in the sub-regulatory guidance regarding the required timeframe to contact the individuals about selecting their enrollment effective date.

Response: Plans determine which election period applies to each individual to assign the proper election period and effective date before the enrollment may be transmitted to CMS. Plans should contact individuals eligible for more than one election period about selecting their enrollment effective date within the timeframes for processing enrollment requests. Sub-regulatory guidance for processing enrollment requests in sections 40.3 of Chapter 2 of the Medicare Managed Care Manual and 40.3 of the Chapter 3 of the Medicare Prescription Drug Benefit Manual explains the timeframe for processing and transmitting election requests to CMS. Plans are required to submit the information necessary for CMS to add the individual to its records as an enrollee of the MA organization or PDP sponsor within 7 calendar days of receipt of the completed enrollment request.

Comment: A commenter stated that allowing dually eligible beneficiaries to choose the election period that results in a desired effective date for MA or Part D could influence utilization patterns and impact associated costs for health care services. The commenter added that changes to enrollment periods and requirements could result in member disenrollment or churn, which may affect the financial stability of MA organizations.

Response: While we appreciate the feedback, we do not believe this change would have such an impact on utilization patterns and associated costs for health care services. This change allowing the beneficiary to choose the election period that results in the desired effective date codifies longstanding sub-regulatory guidance and has been previously implemented by plans. Therefore, we expect that codifying this proposal will have minimal impact on plans' current enrollments.

After consideration of all public comments, for the reasons described here and in the November 2023 proposed rule, we are finalizing our proposal at §§ 422.68(g) and 423.40(f) without modification.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Marketing

A. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (§§ 422.2274(g) and 423.2274(g))

In the December 2022 proposed rule, CMS proposed to add a new paragraph (4) at §§ 422.2274(g) and 423.2274(g) to address issues with third party marketing organizations (TPMOs) distributing beneficiary contact information to other TPMOs, in any manner, including selling this information.[121] In paragraph (4), we proposed that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs. We explained that when a beneficiary calls a 1–800 number from a direct mail flyer, a television advertisement, or an internet advertisement, or other similar material, the beneficiary most likely believes they are only responding to or calling—and requesting contact with—the entity that advertised the 1–800 number and answers the call. However, some of these entities, in quickly read disclaimers or through web or printed material-based disclaimers in very small font, inform the beneficiary that their personal contact information may be sold or distributed to other entities. The contact information (name, address, phone number) obtained by these entities is then sold or distributed to one or more TPMOs, such as field marketing organizations and/or agents/brokers. As a result, these other entities then reach out or 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. We asserted that when a beneficiary calls an entity based on an advertisement, the beneficiary is only expecting to connect with that particular entity, not to have return calls made to their personal home or cell number from other entities.

As discussed in the December 2022 proposed rule, CMS has learned through environmental scanning efforts 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 did not believe that beneficiaries knowingly gave their permission to receive multiple calls from multiple different entities based on a single call made by a beneficiary and that beneficiaries intended in these scenarios that their information would be received only by one entity, that being the plan or agent or broker that will ultimately receive the beneficiary's enrollment request. As another example of this type of behavior, we noted in the December 2022 proposed rule that CMS was aware of situations where entities require the beneficiary to agree to allowing their contact information to be resold or shared prior to speaking with a representative or having access to any information. In these situations, a beneficiary initiates contact with one entity and then ends up receiving calls from multiple other unrelated entities. Additionally, we asserted that providing a quickly read disclaimer or providing a disclaimer in very small print or placing a disclaimer in an inconspicuous place when that disclaimer indicates that a beneficiary's contact information may be provided or sold to another entity or party, are considered misleading marketing tactics because these entities are using beneficiary contact information in a manner in which the beneficiary did not intend.

In order to address this type of activity, we proposed to add a new paragraph (4) to §§ 422.2274(g) and 423.2274(g) that would prohibit TPMOs from distributing any personal beneficiary data that they collect to other TPMOs. In the December 2022 proposed rule, we noted that this proposal was consistent with the statutory prohibition on unsolicited contact contained within sections 1851(j)(1)(A) and 1860D–04(l)(1) of the Act, as well as the corresponding CMS regulations at 42 CFR 422.2264(a)(3) and 423.2264(a)(3). In addition, we note that CMS's authority to promulgate rules related to TPMOs in this circumstance also derives from sections 1851(h)(4)(C)

[121] 87 FR 79535.

and 1860D–01(b)(1)(B)(vi) of the Act, which allow CMS to establish fair marketing standards that shall not permit MA organizations and Part D plans (and the agents, brokers, and *other third parties representing such organizations)* to conduct the prohibited activities described in subsection 1851(j)(1) of the Act. Likewise, we rely in this situation on sections 1856(b)(1), 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which grant the Secretary authority to establish by regulation other standards that are consistent with and carry out the statute and to include additional contract terms and conditions that are not inconsistent with the statute and that the Secretary finds necessary and appropriate.

As noted above, CMS proposed in the December 2022 proposed rule to modify §§ 422.2274(g) and 423.2274(g) to prohibit TPMOs from distributing personal beneficiary data to other TPMOs. However, in light of the comments received on our proposal, which we discuss further below, and for the reasons discussed in our responses, we are instead finalizing § 422.2274(g)(4) and 423.2274(g)(4) with revisions compared to our proposal in the December 2022 proposed rule, which will permit TPMOs to share personal beneficiary data with other TPMOs for marketing or enrollment purposes only if they first obtain express written consent from the relevant beneficiary. In our below responses to comments received regarding the proposed changes to §§ 422.2274(g)(4) and 423.2274(g)(4), we further articulate what TPMOs will be required to do to conform with this consent requirement, including what should be included in a disclosure to beneficiaries.

We acknowledge that other agencies regulate certain types of information collection and sharing of personal information, such as the Department of Health and Human Services' Office for Civil Rights (OCR), the Federal Trade Commission (FTC), and the Federal Communications Commission (FCC). OCR administers and enforces the HIPAA Privacy Rule (45 CFR parts 160 and 164 subparts A and E) which provides standards for the use and disclosure of protected health information by HIPAA covered entities and business associates. A covered entity is a health care provider that conducts certain health care transactions electronically, a health plan, or a health care clearinghouse, while a business associate is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information.[122] Generally, protected health information is individually identifiable health information maintained or transmitted by a covered entity or its business associate. The definitions of a covered entity, business associate, and protected health information can be found at 45 CFR 160.103. The HIPAA Privacy Rule requires that covered entities enter contracts or other arrangements with their business associates to ensure that the business associates will appropriately safeguard protected health information.[123] A covered entity or business associate can share protected health information with a telemarketer only if the covered entity or business associate has either obtained the individual's prior written authorization to do so or has entered into a business associate relationship with the telemarketer for the purpose of making a communication that is not marketing, such as to inform individuals about the covered entity's own goods or services.[124] If the telemarketer is a business associate under the HIPAA Privacy Rule, it must agree by contract to use the information only for communicating on behalf of the covered entity, and not to market its own goods or services (or those of another third party).[125]

As such, it becomes relevant for this final rule whether TPMOs are covered entities or business associates that must comply with the HIPAA Privacy Rule. TPMOs (as defined at § 422.2260) have varying degrees of business and contractual arrangements with MA organizations and Part D sponsors (who are covered entities under the HIPAA Privacy Rule) and may or may not be considered business associates under the HIPAA Privacy Rule. It is the responsibility of the TPMO to understand whether they are a covered entity or acting as a business associate when collecting personal beneficiary data that meets the definition of protected health information. If the TPMO is a covered entity or business associate, the TPMO must ensure they are compliant with the HIPAA Privacy, Security, and Breach Notification Rules when using or disclosing an individual's protected health information.

On December 13, 2023, in the Second Report and Order[126] (*FCC 23–107*), the FCC amended consent rules for robotexts and robocalls governed by the Telephone Consumer Protection Act (TCPA). In the order, FCC made it clear that texters and callers subject to the TCPA must obtain a consumer's prior express written consent when telemarketing via robocall or robotext and that the requirement applies a single seller at a time.[127] Furthermore, the rule made clear that ''the consumer's consent is not transferrable or subject to sale to another caller because it must be given by the consumer to the seller.'' [128] Sharing many concerns that CMS articulated in the December 2022 proposed rule[129] and this final rule, the FCC explained that ''lead generated communications are a large percentage of unwanted calls and texts and often rely on flimsy claims of consent and result in consent abuse by unscrupulous robotexters and robocallers.'' [130] The TCPA generally requires callers to get consumer consent before making certain calls or texts to consumers using an ''automatic telephone dialing system'' (also known as an ''autodialer'') or an artificial or prerecorded voice. 47 U.S.C. 227(b)(1)(A).[131] This new rule, once effective, will require lead generators and comparison-shopping websites to obtain one-to-one consent with a clear and conspicuous disclosure from the consumer for each seller that intends to

[122] 45 CFR 160.103.

[123] 45 CFR 164.502(a).

[124] United States Department of Health and Human Services, Office for Civil Rights: *Can telemarketers obtain my health information and use it to call me to sell good and services?, https://www.hhs.gov/hipaa/for-individuals/faq/277/can-telemarketers-obtain-my-health-information-and-use-it/index.html.* Last reviewed January 9, 2023.

[125] United States Department of Health and Human Services, Office for Civil Rights: *Can telemarketers obtain my health information and use it to call me to sell good and services?*

[126] *Federal Communications Commission, FC–23–107: Second Report and Order, Second Further Notice of Proposed Rulemaking in CG Docket NOS. 02–278 and 21–402, and Waiver Order in CG Docket no. 17–59, https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.* Released December 18, 2023.

[127] Federal Communications Commission, FC–23–107, Page 12 of FCC 23–107. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.* The content of the call or text determines whether the prior express consent from the called party must be in writing.

[128] Federal Communications Commission, FC–23–107, Page 21. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[129] 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.

[130] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[131] Federal Communications Commission, *Telephone Consumer Protection Act 47 U.S.C. 227,* RESTRICTIONS ON THE USE OF TELEPHONE EQUIPMENT. *https://www.fcc.gov/sites/default/files/tcpa-rules.pdf.*

make a call or send a text using an automatic telephone dialing system or make a call containing an artificial or prerecorded voice.[132] Therefore, even if a lead generator or comparison-shopping website lists multiple sellers on its web page, each seller is responsible for obtaining the prior express written consent from the called party through a ''clear and conspicuous'' disclosure on the lead generator or comparison-shopping website in order to robocall or robotext the consumer. The changes to the FCC consent rules also require that telemarketing texts and calls that result from consumer consent must be ''logically and topically associated with the interaction that prompted the consent.'' [133] The FCC explained that this requirement makes ''it clear that sharing lead information with a daisy-chain of ''partners'' is not permitted.'' [134] The FCC refers to these changes as ''closing the lead generator loophole'' [135] which will go into effect at a later date, either 12 months after publication in the **Federal Register**, or 30 days after notice that the Office of Management and Budget has completed review of any information collection requirements.[136] These new FCC rules will apply to TPMOs operating in the MA and Part D marketplace that seek to contact Medicare beneficiaries with advertisements or telemarketing messages using an automatic telephone dialing system or an artificial or prerecorded voice.

The FTC also enforces rules and regulations that apply to TPMOs, such as the Telemarketing Sales Rule (TSR) [137] (16 CFR 310) and Section 5 of the FTC Act (FTCA). The TSR is a set of regulations that apply to telemarketing and generally prohibits abusive and deceptive tactics in marketing. Section 5 of the FTCA provides that unfair or deceptive acts or practices in or affecting commerce are declared unlawful (15 U.S.C. 45(a)(1)).[138] We note that the regulations in this rule do not attempt to change or define what is unlawful under OCR, FCC, or FTC regulations; we are reiterating that TPMOs operating in the MA and Part D marketplace must comply with numerous laws and regulations that govern information sharing, disclosure, and consent to be contacted for marketing or enrollment purposes. The limitations being adopted under the MA and Part D statutes in these MA and Part D regulations are not replacements for other protections for individual information collected in the course of marketing or enrollment, but supplement those protections with specific limitations and restrictions to protect Medicare beneficiaries so that CMS can take steps within its authority under Title 18 [139] to protect Medicare beneficiaries (rather than deferring to other agencies to enforce other requirements that offer similar protections).

We received the following comments on this proposal and our responses follow:

Comment: We received several comments that the proposal disregards a beneficiary's choice on whether to opt in to having their personal contact information shared. While some commenters were largely supportive of the total prohibition, citing the protections to beneficiary privacy and autonomy, many commenters believed that beneficiaries should be able to consent to having their information shared. A few commenters stated that TPMOs should be able to share beneficiary contact information when the beneficiary knowingly consents and requests to have it shared, which would not be possible if the rule was finalized as proposed. Another commenter stated that the statute expressly gives beneficiaries the right to solicit direct contacts, and if CMS implemented this new requirement, without any ability for them to consent, that right to permit direct contacts would be taken away from the beneficiary. Some commenters suggested that rather than implementing a full prohibition on sharing information, CMS could introduce measures to clarify how to request consent for the sharing of beneficiary information to multiple entities. Commenters provided suggestions on how to ensure beneficiaries knowingly consent to having their data shared, which included adopting the FTC's clear and conspicuous standard, limitations on who may contact a beneficiary, and how often or for how long a beneficiary may be contacted. A few commenters believed that CMS incorrectly assumes a beneficiary never wants their information to be shared, or that they are unable to make that choice. A commenter agreed that stronger consent is needed, but disagreed with the CMS claim that beneficiaries are not aware that they are opting into their information being shared with multiple entities. Commenters also suggested including more effective disclosures or disclaimers that indicate the resale and/or the specific details of where and to whom this information will be shared. A commenter provided their standards as a resource, which listed the different standards they currently utilize.

Response: CMS thanks commenters that were supportive of our proposal to prohibit the sharing of beneficiaries' personal information and appreciates the various suggestions that commenters provided to allow beneficiaries to consent to the sharing of their personal information. We recognize that other statutory and regulatory frameworks, such as the TCPA, TSR, and HIPAA Privacy Rule, which deal with sharing personal information and contacting consumers, allow individuals to consent to the sharing of their information or the receipt of calls from product and service providers. Equally as important, we recognize the right of beneficiaries to share their personal information and that some may want to share their information with many TPMOs to solicit direct contact from a larger group of TPMOs to assist them in selecting a health plan that best meets their needs. Therefore, we agree with the commenters that beneficiaries should be able to consent to having their personal information shared in a clear and understandable way and have modified the proposed regulation text to provide for this option. In this final rule and based upon suggestions received in comments, we are codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Further, we are codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure. We believe that beneficiaries have the right to share their personal data with whom they choose and should have the opportunity

[132] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[133] *Federal Communications Commission, FC–23–107,* Page 51. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[134] *Federal Communications Commission, FC–23–107,* Page 14. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[135] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[136] *Federal Communications Commission, FC–23–107, VII. ORDERING CLAUSES,* Page 39. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[137] *https://www.ecfr.gov/current/title-16/part-310.*

[138] *https://uscode.house.gov/view.xhtml?req=(title:15%20section:45%20edition:prelim)%20OR%20(granuleid:U.S.C.-prelim-title15-section45)&f=treesort&num=0&edition=prelim.*

[139] *https://www.ssa.gov/OP_Home/ssact/title18/1800.htm.*

to fully understand with whom their personal data may be shared. By finalizing the rule in this way, we are not codifying an outright prohibition of sharing personal beneficiary data. CMS sought technical studies on the results of limiting beneficiary data sharing and its effectiveness. For example, in a 2023 Pew Survey, CMS learned from Pew's findings that ''overall, 72% [of Americans] say there should be more government regulation of what companies can do with their customers' personal information.'' [140] The survey also revealed that ''a majority of Americans say they are concerned, lack control and have a limited understanding about how the data collected about them is used.'' [141] No studies that we can find exist on whether completely limiting the distribution improves the beneficiary experience. We have, however, numerous complaints, both through 1–800-Medicare, the new FCC Second Report and Order [142] cited earlier, as well as State Health Insurance Programs, testimony from health insurance administrators and executives,[143] and advocacy groups noting that the overwhelming number of marketing calls beneficiaries receive from TPMOs are unwanted, confusing, and inhibit the beneficiary's ability to make an informed choice. Our final rule aims to limit when a beneficiary's personal data can be shared and ensures that they know who will be contacting them, which we believe will lower the number of complaints, be less overwhelming, and will result in beneficiaries having a more meaningful discussion with fewer agents, and ultimately enrolling in a health plan that best meets their needs.

We are codifying the regulation text in a way that is generally consistent with the one-to-one consent structure announced by the FCC in the Second Report and Order [144] (*FCC 23–107*) in order to make it simple and less arduous for a TPMO to comply with both rules, when applicable. The FCC's Order amends the definition of prior express written consent at 47 CFR 64.1200 for a person to be called or texted advertisements or telemarketing messages using an automatic telephone dialing system or an artificial or prerecorded voice by requiring an agreement, in writing, that bears the signature of the person called or texted that clearly and conspicuously authorizes no more than one identified seller. The FCC explained that if a lead generator or comparison-shopping website seeks to obtain prior express written consent for multiple sellers, they must obtain prior express written consent separately for each seller. Secondly, the FCC Order requires a written agreement that includes a clear and conspicuous disclosure informing the person signing that they are authorizing the seller to deliver or cause to be delivered to the signatory telemarketing calls or texts using an automatic telephone dialing system or an artificial or prerecorded voice. The FCC defined clear and conspicuous as ''notice that would be apparent to a reasonable consumer.'' [145]

We believe that prior express written consent, one-to-one from person to seller, through a clear and conspicuous disclosure to share personal beneficiary data with another TPMO, is a reasonable and less restrictive standard than a ''complete prohibition'' on the sharing of personal beneficiary data with other TPMOs. This consent and disclosure are necessary to provide beneficiaries with the information they need to understand where their personal data is going, what they are consenting to being contacted about, and who will be contacting them for health care options. Prior express *written* consent will ensure that there is a record of the beneficiary consenting to the sharing of their data, which can easily be obtained through a website interface, but can also be provided through email or text message when a beneficiary calls a toll-free number. By adopting the one-to-one consent requirement, we will prevent TPMOs from having to build a different consent and disclosure structure on their websites and systems because it aligns with the one-to-one consent structure in the FCC rules on consenting to telemarketing calls or texts using an automatic telephone dialing system or an artificial or prerecorded voice. Under the FCC's new rules, if a TPMO marketing MA or Part D plan options wants to robotext or robocall a beneficiary, they must obtain consent from the beneficiary that they agree for that specific entity to contact them via robotext or robocall. Similarly, under our amended rule, if a TPMO wants to share a beneficiary's personal data with another TPMO, the TPMO must obtain consent from the beneficiary for each entity that it intends to share the data with. Thus, the shared one-to-one consent structure will make it easier for TPMOs to collect both consents at the same time; a consent to share the beneficiary's personal data with a specific entity and the consent for that entity to robotext, robocall, or call the beneficiary, as applicable.

In addition, this rule will prevent the sharing of personal beneficiary data with another TPMO unless expressly authorized by the beneficiary, which means beneficiaries will not be called by TPMOs with whom they have not given permission to be called, even when the new FCC rule does not apply (*i.e.,* a manually dialed phone call). Finally, the regulation requires a ''clear and conspicuous'' disclosure to the beneficiary, which is a standard used in the FCC Order as well as by the FTC as defined at 16 CFR 255.0(f). Under 16 CFR part 255—Guides Concerning Use of Endorsements and Testimonials in Advertising, the FTC defines clear and conspicuous to mean ''that a disclosure is difficult to miss (*i.e.,* easily noticeable) and easily understandable by ordinary consumers.'' [146] The FTC also provides numerous examples to illustrate how the definition of clear and conspicuous is applied in real life examples in Part 255.[147] We find the FCC and FTC definition of clear and conspicuous to be similar but point to the FTC's definition as guiding for our rule because the definition has been recently updated [148] and there are numerous examples that can help guide TPMOs in how to apply it.

We understand that sometimes a beneficiary can be connected to another TPMO in real time. For example, a beneficiary may call a TPMO seeking to get information about Medicare plan options and that TPMO, in order to assist the beneficiary, may be able to

[140] Pew Research Center, *How Americans View Data Privacy: Views of data privacy risks, personal data and digital privacy laws. https://www.pewresearch.org/internet/2023/10/18/views-of-data-privacy-risks-personal-data-and-digital-privacy-laws/.*

[141] Pew Research Center, *How Americans View Data Privacy: Views of data privacy risks, personal data and digital privacy laws. https://www.pewresearch.org/internet/2023/10/18/views-of-data-privacy-risks-personal-data-and-digital-privacy-laws/.*

[142] Federal Communications Commission, *FC–23–107. https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[143] United States Senate Committee on Finance, *Medicare Advantage Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences. https://www.finance.senate.gov/hearings/medicare-advantage-annual-enrollment-cracking-down-on-deceptive-practices-and-improving-senior-experiences.*

[144] *Federal Communications Commission, FC–23–107. https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[145] *Federal Communications Commission, FC–23–107, Page 16. https://docs.fcc.gov/public/attachments/FCC-23-107A1.*

[146] *https://www.ecfr.gov/current/title-16/part-255#p-255.0(f).*

[147] *https://www.ecfr.gov/current/title-16/part-255#p-255.0(f).*

[148] Federal Trade Commission, *Guides Concerning the Use of Endorsements and Testimonials in Advertising (88 FR 48092),* updated July 26, 2023.

transfer or connect that beneficiary to another TPMO, such as an agent or broker during the call to provide real time assistance to the beneficiary. In that circumstance, where a live call can be transferred to another entity for assistance, we believe this is an acceptable approach that can be accomplished without obtaining prior express written consent as long as the beneficiary has verbally agreed or consented to be transferred during the live phone call. For purposes of this rule, we do not believe that transferring a live phone call from the beneficiary to an agent or broker that can provide immediate assistance to the beneficiary is considered ''sharing personal beneficiary data,'' which would require prior express written consent under our rule. However, if the TPMO would need to share a beneficiary's personal data with anyone that the beneficiary will not immediately be speaking with, they will need to comply with our rule and receive prior express written consent from the beneficiary to share their personal data.

Our final rule applies when personal beneficiary data is collected by a TPMO for purposes of marketing or enrolling them into an MA plan or Part D plan. Therefore, if a TPMO collects a beneficiary's personal beneficiary data with the purpose of eventually marketing or enrolling that beneficiary into an MA or Part D Plan, it would be inappropriate for that TPMO to share the beneficiary's data with a second TPMO without the beneficiary's consent, even if that second TPMO does not plan to conduct any marketing or enrollment activities. If the beneficiary's data was collected and sold with the purpose of eventually marketing to the person or enrolling them into an MA or Part D plan (*i.e.* a sales lead), then the beneficiary must consent to the sharing of that data with each TPMO that is involved in the marketing or enrollment chain. Finally, we note that selling personal beneficiary data may implicate the Federal anti-kickback statute.

Comment: A few commenters questioned CMS's statutory authority to limit beneficiary data sharing. Some commenters stated that the currently cited statutory authority does not address the distribution of personal beneficiary data and additionally, that under that authority, unsolicited outreach is already prohibited. This commenter stated the statute applies to all entities, and not just TPMOs, while CMS's proposal applies solely to TPMOs. A commenter requested that CMS clarify that it does not prohibit TPMOs from sharing directly with MA–PD plans and sponsors.

Response: We are finalizing changes to §§ 422.2274(g) and 423.2274(g) based on the statutory authorities at §§ 1851(j)(1)(A) and 1860D–04(l)(1) of the Act that prohibit unsolicited means of direct contact, as well as §§ 1851(h)(4)(C) and 1860D–01(b)(1)(B)(vi) of the Act, which allows CMS to establish fair marketing standards that shall not permit MA organizations and Part D plans (and the agents, brokers, and other third parties representing such organizations) to conduct the prohibited activities described in subsection 1851(j)(1) of the Act. Further, we rely in this situation on sections 1856(b)(1), 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which grant the Secretary authority to establish by regulation other standards that are consistent with and carry out the statute and to include additional contract terms and conditions that are not inconsistent with the statute and that the Secretary finds necessary and appropriate. Based on these authorities and comments received on our proposal that have informed this final rule, we are requiring that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. This is necessary to prevent abusive practices by TPMOs that inundate beneficiaries with unwanted phone calls, text messages, and emails. Furthermore, this rule is consistent with the MA and Part D statutes because the restriction on sharing personal beneficiary data is limited to data collected for the purposes of marketing or enrollment.

As a commenter pointed out, the statute that prohibits certain marketing practices at § 1851(h)(4)(C) applies to MA organizations or *the agents, brokers, and other third parties representing such organization.* CMS has defined TPMOs to mean organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.[149] Therefore, the definition of TPMO broadly encompasses third parties involved in the marketing and enrollment functions and is a term that applies to entities that are prohibited from engaging in prohibited acts described in 1851(j)(1)(A) of the Act. We clarify here that the definition of TPMO does not apply to MA organizations or Part D sponsors, and therefore TPMOs may share personal beneficiary data with those entities without acquiring direct consent from the beneficiary under this rule. As noted earlier, covered entities and business associates would still need to ensure they are complying with HIPAA privacy rules when sharing personal beneficiary data.

Comment: Commenters stated that data distribution is already governed by other statutes that conflict with CMS's proposal. A commenter stated CMS did not explain how ''personal beneficiary data'' sits alongside data sets such as Personally Identifiable Information (PII), Personal Health Information and Personal Health Records as well as how the proposed rule comports with other applicable statutes, like the Telephone Consumer Protection Act (TCPA), which is enforced by the Federal Communications Commission (FCC), and the Telemarketing Sales Rule (TSR), which is enforced by the Federal Trade Commission (FTC). This commenter stated that, if finalized, CMS's proposal would essentially remove that right to consent to share their data that is provided through these other statutes. Lastly, a commenter noted that TPMOs and other industry participants distribute personal beneficiary data for reasons unrelated to direct contact with beneficiaries, such as for modeling, technology development, and other purposes unrelated to direct contact with beneficiaries.

Response: As previously discussed, our final policy does not take away a beneficiary's ability to consent to the sharing of their personal data. We are finalizing a modified policy that allows for personal beneficiary data to be shared where the TPMO has obtained prior express written consent from the beneficiary for each TPMO that will receive the data. Our modified policy provides beneficiaries with the ability to consent to their personal beneficiary data being shared, as is consistent with other agencies such as the FCC and FTC. At the same time, the ability for beneficiaries to provide express written consent for each TPMO strengthens beneficiary protections, by giving them more control over who can receive their contact information and how many TPMOs can contact them. We understand that TPMOs must comply with other statutes and regulations such as the HIPAA Privacy Rule, TCPA, and

[149] 42 CFR 422.2260.

TSR, and these informed our final policy in this rule. In the December 2022 proposed rule, we described ''personal beneficiary data'' as ''contact information,'' such as name, address, and phone number. We further clarify here that ''personal beneficiary data'' includes contact information but could also include any other information given by the beneficiary for the purpose of finding an appropriate MA or Part D plan. As examples, this could include health information or other personal information such as age, gender, or disability. For purposes of this rule, we describe the information collected from a beneficiary by a TPMO as ''personal beneficiary data.'' We are not attempting to classify this information as PII or PHI, which can have more specific meanings and definitions, such as those used in the HIPAA Privacy Rule. We recognize that the HIPAA Privacy Rule contains very specific disclosure and authorization rules that are more stringent than what we are finalizing in this rule, such as when it comes to covered entities or their business associates sharing information covered under the HIPAA Privacy Rule. We reiterate that the HIPAA Privacy Rule must be followed by TPMOs that are covered entities or business associates under the HIPAA Privacy Rule and it is the responsibility of the TPMO to determine their status as either a covered entity or business associate. A valid authorization under the HIPAA Privacy Rule must specify the name or other specific identification of the person, or class of persons, to whom the covered entity or business associate may make the requested use or disclosure. Since the recipient entities are specifically identified in a valid authorization such that an individual signing an authorization clearly understands the intended recipients, we would consider a disclosure pursuant to a valid authorization also compliant with our rule at §§ 422.2274(g) and 423.2274(g).

TPMOs that engage in the marketing and enrollment of Medicare beneficiaries must also comply with other rules that govern telephonic marketing and communication. The TCPA, governed by the FCC, restricts making telemarketing calls and texts with automatic telephone dialing systems or artificial or prerecorded voice. Similarly, the TSR, governed by the FTC, generally prohibits initiating any outbound telephone call that delivers a prerecorded message unless the seller has obtained from the recipient of the call an express agreement, in writing, that the seller obtained only after a clear and conspicuous disclosure that the purpose of the agreement is to authorize the seller to place prerecorded calls to such person.[150] Therefore, TPMOs must follow those rules when they engage in those kinds of activities (*i.e.,* calling leads through an automatic telephone dialing system using random number generation, using pre-recorded messages). However, TPMOs can also conduct telemarketing in ways that are not governed by the TCPA, such as by manually dialing a lead number and using a customer service or salesperson to speak with the person that answers the phone. Our final regulation seeks to place limits on the sharing of the personal beneficiary data collected by a TPMO in a way that allows TPMOs to develop disclosure and consent processes that easily conform to all applicable rules that may apply. By using a one-to-one consent structure in our rule, TPMOs may obtain permission to share personal beneficiary data with another TPMO at the same time they acquire permission to have that TPMO contact the beneficiary, which could fall under FTC or FCC rules depending on how the contact is made. Further, by requiring the TPMO to obtain prior express written consent from the beneficiary to share their personal data and be contacted for marketing or enrollment purposes through a clear and conspicuous disclosure for each TPMO, it ensures that the beneficiary has control over who is allowed to access their information. This also ensures that any manually dialed calls (calls that are not subject to consent rules under TCPA) that occur because a marketing lead was shared also have been consented to by the beneficiary.

As described at §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv), an MA organization, Part D sponsor or its agents and brokers may not make unsolicited telemarketing calls, and §§ 422.2264(a)(3) and 423.2264(a)(3) explains that calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. By requiring TPMOs to obtain a beneficiary's consent to be contacted along with their consent to share their personal data for purposes of marketing or enrollment, we are ensuring that any entity that receives the lead information that includes personal beneficiary data, has appropriate permission by way of one-to-one consent from the beneficiary to contact them in accordance with §§ 422.2264(a)(3) and 423.2264(a)(3). We note that rules at §§ 422.2264(b) and 423.2264(b) describe when MA organizations or Part D sponsors may contact current and former enrollees to discuss plan business. Calls that qualify as ''plan business'' are not considered ''unsolicited'' but in accordance with §§ 422.2264(b)(2) and 423.2264(b)(2), MA organizations and Part D sponsors 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.

A commenter pointed out that TPMOs share beneficiary data for reasons unrelated to direct contact with beneficiaries. For example, a TPMO could collect a beneficiary's personal data and have no intention of directly contacting them. They could sell it, use it for modeling or technology development, or for some other purpose. Ultimately, that information was provided by the beneficiary to assist in helping them select a health plan, and therefore prior express written consent to share that data with another TPMO must be given by the beneficiary under this rule. Our primary justification for imposing these data restrictions is to reduce or eliminate unwanted calls that potential enrollees are receiving from agents and brokers or other TPMOs. Therefore, if the data is de-identified or redacted in a way where the data cannot be used to contact the beneficiary as a potential sales lead, and the purpose of the data sharing is not related to marketing or enrollment, a TPMO can share the de-identified data with other TPMOs without prior express written consent. We are concerned that allowing the sharing of the full data under the guise of ''modeling'' or technology development'' could be abused by TPMOs as a means to move potential sales leads without consent. We reiterate that it makes no difference if the TPMO collects the personal beneficiary data without any intention of directly contact that person. It would be non-compliant with this rule to share the personal beneficiary data with another TPMO without prior express written consent from the beneficiary.

Comment: CMS received many comments on how this proposal would impact beneficiaries. Some commenters expressed support for the proposal and noted that, if finalized, this proposal would provide greater privacy and protection to beneficiaries from receiving an unreasonable number of marketing calls and inquiries. Additionally, a commenter stated that beneficiary autonomy and the ability to direct how they get information should take precedence over the business interests of lead generating companies

[150] 16 CFR 310.4(b)(v).

and those who use or purchase their information.

Response: We thank the commenters for their support. We value the importance of beneficiaries having greater privacy as well as autonomy over their contact information and who it is shared with, especially when it is used to contact them. By balancing beneficiary protections with beneficiary choice, we believe that this final rule will have a strong positive impact on beneficiaries who have been struggling with the volume of unwanted phone calls, texts, and emails. This rule enables beneficiaries to decide what best meets their health care needs by controlling who contacts them and for what purposes. If a beneficiary wants to provide consent to be contacted by multiple TPMOs, this rule ensures they have that flexibility. However, if a beneficiary is only seeking to speak with one or two TPMOs, our rule ensures that the beneficiary will not receive unwanted and unsolicited calls or be misled by difficult to read disclaimers. TPMOs should use a consent method where the default selection is that the beneficiary chooses to not share their data; there should be an affirmative action by the beneficiary to acknowledge that sharing their data with another TPMO is permitted. By being able to consent to each listed TPMO through a clear and conspicuous disclaimer, beneficiaries can make informed decisions that best fit their personal preference.

Comment: Some commenters expressed concern that this proposal would place a greater burden on beneficiaries. Without a TPMO's ability to distribute a beneficiary's personal data to another TPMO, these commenters believed beneficiaries would have fewer opportunities to receive information about plan options available to them, which would limit their plan options as well as their ability to find the best plan for their needs. As a commenter explained, beneficiaries are in a better position speaking with a broker that can sell many MA plans rather than an agent that can only sell one plan. Another commenter stated that under CMS's proposal, beneficiaries would have to identify each agent that represents the plans they are interested in, and if unable to do so, the beneficiaries would have to contact each individual plan to obtain plan benefit information.

Response: CMS appreciates commenters for sharing their concerns regarding how beneficiaries' access to plan information and options would change under this proposal. We appreciate the commenters for providing insight into the ways TPMOs use beneficiary data, such as some TPMOs' reliance on sharing personal data multiple times in order to connect beneficiaries with the agent or broker that can best assist the beneficiary. We agree that many TPMOs have an important role to play in making it easier for beneficiaries to find the plan that best fits their needs. As noted above, we have modified our proposal to allow TPMOs to continue sharing a beneficiary's data as long as they obtain prior express written consent, through a clear and conspicuous disclaimer, for each TPMO that will receive the beneficiary's information and contact them. We have received many complaints regarding the high volume of unwanted calls beneficiaries are experiencing, which can be distressing and confusing to beneficiaries when trying to enroll in a plan. By having the ability to provide clear consent to the TPMOs they with whom they would like to speak, this new rule will make it easier for beneficiaries to control who is contacting them and provide beneficiaries with a clearer understanding of what they are consenting to prior to being contacted. TPMOs can still connect beneficiaries with agents and brokers or other TPMOs with the new guarantee that the beneficiary is consenting to speak with that specific entity. At the same time, this rule creates a safer and clearer environment for the beneficiary to find the best health plan for their needs, by ensuring they do not receive unwanted or unsolicited phone calls. Additionally, we believe this rule will provide an opportunity for TPMOs to continue to make the experience more user friendly and accessible for all beneficiaries, as beneficiaries shouldn't need to opt in to potentially receiving calls from an unknown number of TPMOs in order to compare plans and find the plan that best fits their needs.

CMS understands the important role TPMOs can play in determining which is the best plan to meet a beneficiary's health needs. In this final rule, the beneficiary can still opt in to having their information shared with as many TPMOs as they'd like. A clear and conspicuous disclaimer will ensure that for each authorization for contact a beneficiary provides, they have full knowledge of who is receiving their information and the ability to knowingly and clearly consent to being contacted by this entity. We agree with commenters that beneficiaries should be able to easily and simply access information about plan options but disagree that putting some safeguards on how a beneficiary's personal data is shared will put a greater burden on beneficiaries. This final rule ensures that the beneficiary has the choice and ability to decide whether and who can contact them, while allowing TPMOs to continue supporting consenting beneficiaries by connecting them to the appropriate people that can help the beneficiary enroll in a plan that best meets their health care needs.

Comment: CMS received comments discussing the adverse impact of this proposed rule on TPMOs and the Medicare Advantage (MA) industry. Some commenters were concerned that CMS's proposal to prohibit the distribution of personal beneficiary data would result in entities, including individual insurance agencies, being put out of business. Commenters stated that leads are necessary to market, with a few commenters mentioning that individual agents or agencies do not have the bandwidth or financial means to perform lead generation, marketing, or communications on their own. A few commenters were concerned about how this would impact TPMOs and insurance agencies' ability to connect beneficiaries with an agent or broker. As one commenter stated, lead generators offer one of the main mechanisms to identify interested beneficiaries and connect them with the agents and brokers who represent plans in their area. Other commenters were concerned about the impact on marketing activities of agents and brokers, stating that if this proposal were finalized, agents and brokers would be unable to rely on marketing specialists that connect them with beneficiaries. One commenter stated that this proposed change would be detrimental because these specialists have the expertise and technology to navigate the health care options and connect beneficiaries with an agent. Another commenter stated that this provision would fundamentally change the current market by severely limiting legitimate pre-enrollment business engagement between first tier entities and downstream and related entities.

Response: CMS understands commenters' concerns about how this might affect the TPMO industry and specifically, the TPMOs that support MA organizations and Part D sponsors. We acknowledge that a complete prohibition on beneficiary data sharing would be detrimental to the TPMO industry and could adversely impact beneficiaries access to expertise when navigating their plan options. We believe the amended policy will mitigate these concerns and will balance the need to protect beneficiary data. While this final rule may require a shift

in current practices when TPMOs market or enroll beneficiaries, we expect that the overall effect on the industry will be positive as beneficiaries will have stronger protections against unwanted calls and transparency about who is calling them, while still having access to agents and brokers that provide plan options and choice. Our final rule does not place a limit on the number of TPMOs that a TPMO may share personal beneficiary data with, but it does require that a beneficiary consent to each TPMO that will receive their data. Lead generators, field marketing organizations, agents, brokers and other TPMOs will still be able to share a beneficiary's personal data, as long as they ensure the beneficiary consents through a clear and conspicuous disclaimer to each TPMO prior to receiving their data. We understand this may initially have an impact on TPMOs' processes and operations when adjusting to this new method of obtaining one-to-one consent through a clear and conspicuous disclaimer, but CMS is not, through this rule, prohibiting the ability of TPMOs to share personal beneficiary contact data.

We believe TPMOs and beneficiaries will benefit from this rule because it will ensure that beneficiaries are receiving information and being contacted by the entities they explicitly consent to speaking with and TPMOs will be better able to support the individual beneficiary. The clear and conspicuous disclaimer will allow TPMOs to further educate beneficiaries about who they need to be connected with in order to find the best plan for their healthcare needs while ensuring a safer and more engaging environment for beneficiaries. Additionally, this rule applies solely to sharing personal beneficiary data for the purposes of marketing or enrollment and ensures that TPMOs are still able to share this data for other activities, provided they are compliant with other agencies that govern personal information and data sharing (such as the OCR).

We acknowledge that this may shift how some TPMOs currently share personal beneficiary data but there are a variety of approaches that TPMOs can use to ensure obtaining a beneficiary's one-to-one consent is easy, accessible and straightforward for beneficiaries. For example, through a clear and conspicuous disclosure on a website, a TPMO could provide a check box list that allows the beneficiary to choose each TPMO that they want to hear from. We believe beneficiaries are best served by having the ability to affirmatively consent to who is contacting them.

Comment: One commenter argued that the more robust the lead generation environment is, the more competition there is, as lead generators enable compliant companies to stay in the market. The commenter argues that this should mean more competition, which they argue leads to more informative consumer engagement. Another commenter stated that the proposed changes would have a negative economic impact as it would result in less awareness of MA plans and would likely lead to decreased enrollment.

Response: We understand the importance of competition for a successful business but reiterate that our priority is to protect beneficiaries from misleading, inaccurate, or otherwise abusive communication and marketing practices and ensure that they are able to make coverage choices that best meet their health care needs. Our modified policy will mitigate commenter concerns and still allow competition in the marketplace for TPMOs that can operate in accordance with these rules. It will provide a safer environment for beneficiaries and still allow for numerous TPMO options from which a beneficiary may choose to assist in the selection of a health plan. We do not believe that this amended final policy will result in less awareness of MA plans or less enrollment. Beneficiary complaints received by CMS convey to us that beneficiaries are receiving too many calls, causing confusion, resulting in beneficiaries being overwhelmed, and unable to make a good choice for their health care needs. We believe more informative consumer engagement will not come from competition between lead generators, but from beneficiaries being able to consent to each TPMO from which they would like to receive a contact. Moreover, allowing beneficiaries to review a clear and conspicuous disclaimer will empower them with transparent information, greater choice, and personal autonomy.

Comment: A few commenters expressed concern about how the proposed rule limits data sharing among downstream entities, or as some commenters called them, ''affiliated entities.'' One commenter stated that an independent agent could not share personal beneficiary information that the agent collects with another independent agent operating within the same field marketing organization. Another commenter stated that this CMS proposal would limit a plan's ability to distribute personal beneficiary information to their downstream entities, disrupting the hierarchical distribution of leads that match agents with leads and prevent lead duplication. The commenter stated that this chain of data sharing within affiliated entities ensures compliant leads, which is in the best interest of plans and beneficiaries. The commenter stated that the proposal would require TPMOs to generate their own leads, which may mean more duplicate leads or leads without proper consent. A few commenters were concerned that the data sharing prohibition would result in companies being unable to utilize the complex technology TPMOs use to determine what agent can best serve the needs of a specific beneficiary. One commenter mentioned that individual agents and agencies do not have the expertise, resources, and complex technologies to support marketing and outreach that are currently handled by large TPMOs. Some commenters noted that TPMOs provide services to independent agents that they contract with such as training, administrative support, customer service and marketing/lead generation and that this proposal would prevent those TPMOs from providing these services that licensed agents rely on. A commenter noted that TPMOs and other industry participants distribute personal beneficiary data for reasons unrelated to direct contact with beneficiaries, such as for modeling, technology development, and other purposes unrelated to direct contact with beneficiaries.

Response: We thank commenters for their perspectives on how the proposed rule would impact data sharing among affiliated entities, downstream entities, independent agents, and when it could be appropriate to share beneficiary information across these entities. However, because we are amending the policy discussed in the proposed rule, we will discuss these topics in the context of the modified final policy.

Under amended regulations that CMS is adopting in this final rule at §§ 42 CFR 422.2274(g)(4) and 423.2274(g)(4), a TPMO may not share any personal beneficiary data with a TPMO that is a different legal entity unless prior express written consent has been given by the beneficiary. This includes sharing information with another legal entity that shares the same parent organization or has a contract to perform a downstream function of the organization; prior express written consent from the beneficiary is required under both circumstances. We do not believe that just because another entity is ''affiliated'' with an organization, that the organization has the right to share a beneficiary's information with that other entity without the knowing consent of the beneficiary. This includes the sharing of beneficiary data among two

independent agents affiliated with the same FMO. An independent agent that shares personal beneficiary data with another independent agent even if both are affiliated with the same FMO would be out of compliance with our rule, unless prior express written consent is given by the beneficiary. As mentioned earlier, an exception to this is where a beneficiary provides verbal consent on a live phone call to be transferred to another entity for immediate assistance; we believe this is an acceptable approach that can be accomplished without obtaining prior express written consent. However, two agents that work directly for the same FMO as employees (not independent contractors) may share personal beneficiary data as long as the beneficiary has freely given that data to the FMO or it was obtained with the beneficiary's consent.

Comment: CMS received comments addressing CMS's reasons for prohibiting TPMOs from sharing personal beneficiary information with each other. Some commenters were supportive of CMS's proposal and the assertions about this form of misleading marketing, where beneficiaries are being inundated with unwanted phone calls that they are unwittingly consenting to due to vague consent and difficult-to-read disclaimers. As a commenter mentioned, many SHIPs, agencies, beneficiaries, and their families have expressed concern about the misleading and confusing marketing activities conducted by TPMOs.

Response: We appreciate commenters for the support of our proposal and for recognizing the impact of these unwanted phone calls on beneficiaries. We continue to ensure strong beneficiary protections against misleading marketing and communications and being inundated with unwanted phone calls while still ensuring they have access to plan options and choice. Our final rule reflects this balance of beneficiary protection and privacy with beneficiary access to information to inform their choices.

Comment: A few commenters had general issues with our proposal. Some commenters stated that CMS is punishing all TPMOs for the behavior of some bad actors. One commenter suggested CMS is incorrectly assuming that many TPMOs sell beneficiary personal information to multiple unaffiliated entities. The commenter added that while some lead generators or performance marketers may misbehave, not all sales and distribution practices are problematic or should be prohibited. Another commenter argued that agent error is the main cause of most complaints and therefore this proposal would not have any impact.

Response: We understand that many TPMOs and other entities act in good faith to aid beneficiaries in making an informed health care choice. We reiterate that CMS is not punishing TPMOs, but rather creating a more supportive and conducive environment for beneficiaries to access the information they need to make plan decisions while not being inundated with unwanted phone calls. Currently, as we've seen through routine surveillance of TPMO websites and information received from Congressional hearings and testimonies, personal beneficiary data is shared among many TPMOs with no ability for the beneficiary to select who or how many entities with and from whom they wish to consent to contact them. As an example, there are TPMO websites that provide an opportunity for a beneficiary to opt into being contacted and, within a small disclaimer with a lot of small text, includes a hyperlink to over 100 licensed agents/brokers who may all call the beneficiary. The current activities have resulted in numerous complaints by beneficiaries. CMS's final rule provides stronger beneficiary protection while still enabling TPMOs to provide the vital support of ensuring beneficiaries are connected with an agent/broker or other TPMO who can help them find the plan that best fits their needs.

In summary, we are not finalizing the rule as proposed at §§ 422.2274(g)(4) and 423.2274(g)(4) that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs. After considering the comments received in response to this proposal, and for the reasons that we have discussed in our responses, we are finalizing §§ 422.2274(g)(4) and 423.2274(g)(4) with revisions that provide that personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Also, we explain that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO. To align with our other marketing changes for agent broker compensation, and to coincide with the beginning of marketing and enrollment activities for the 2025 contract year, we are delaying the applicability of these changes to §§ 422.2274(g) and 423.2274(g) October 1, 2024. Therefore, any personal beneficiary data shared by a TPMO with another TPMO for purposes of marketing or enrollment must have prior express written consent by the beneficiary beginning on October 1, 2024. This includes beneficiary data that is collected prior to October 1, 2024, but will be transferred or shared with another TPMO on or after October 1, 2024. Simply put, TPMOs must have prior express written consent to share a beneficiary's personal data on or after October 1, 2024.

B. Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267)

Section 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to set standards related to the review of marketing materials and establish limitations on marketing activities, as part of the standards for carrying out the MA program under section 1856(b) of the Act. In the January 2021 final rule, CMS used this statutory authority to codify guidance from the Medicare Communications & Marketing Guidelines (MCMG) into subpart V of part 422 (86 FR 5864). Several commenters in that prior rulemaking urged CMS to add specific provisions in the marketing and communications regulations regarding how MA organizations may market SSBCI described in § 422.102(f). In response, CMS established a new requirement for a disclaimer to be used when SSBCI are mentioned. The SSBCI disclaimer was originally codified at § 422.2267(e)(32), and it currently appears at paragraph (e)(34). Currently, that regulation requires MA organizations to: (i) convey that the benefits mentioned are a part of special supplemental benefits, (ii) convey that not all members will qualify for these benefits; and (iii) include the model content in the material copy which mentions SSBCI benefits. Section 422.2267(e)(34) does not explicitly state that it applies to both marketing and communications materials, but our sub-regulatory guidance is clear that it applies whenever SSBCI are mentioned; the disclaimer is required regardless of whether the material that mentions the benefits is a marketing or communications material. The purpose of the SSBCI disclaimer is to ensure that beneficiaries are aware that SSBCI are not available to all plan enrollees and that the eligibility for these benefits is

limited by section 1852(a)(3)(D) of the Act and § 422.102(f). Ensuring a clear statement of these limitations in a disclaimer will guard against beneficiary confusion or misunderstanding of the scope of SSBCI, and thus lessens the chance that a beneficiary will enroll in a certain plan believing they can access an SSBCI for which they may not ultimately be eligible.

Per the January 2021 final rule, MA organizations were required to comply with the new SSBCI disclaimer requirement for coverage beginning January 1, 2022. Since MA organizations had over a year to implement their use of the SSBCI disclaimer at the time of the November 2023 proposed rule, we took an opportunity to reevaluate the requirement at § 422.2267(e)(34), considering our observation of its actual implementation.

MA organizations market SSBCI by advertising various benefits, including coverage of groceries, pest control, prepared meals, household items, gasoline, utility bills, auto repair, pet supplies or grooming, and more. Although some of these SSBCI items and services may be available under a given plan, the enrollee must meet the criteria established to receive a particular SSBCI. In many instances, MA organizations have been found to use marketing to potentially misrepresent the benefit offered, often not presenting a clear picture of the benefit and limits on eligibility. In a May 2022 letter sent to Congress, the National Association of Insurance Commissioners (NAIC) detailed its findings from surveys with state departments of insurance, showing ''an increase in complaints from seniors about confusing, misleading and potentially deceptive advertising and marketing of these plans.'' [151] Additionally, as discussed in prior rulemaking, CMS has seen an increase in complaints related to marketing, with more than twice as many complaints related to marketing in 2021 compared to 2020.[152] As evidenced by complaints CMS has received, some of the current marketing of SSBCI has the potential to give beneficiaries the wrong impression by leading them to believe they can automatically receive all SSBCI available by enrolling in the plan.

CMS has seen multiple examples of such misleading SSBCI ads among MA organizations. We have seen ads (for example, online, billboards, television) in which the MA organization presents an extensive list of benefits that are available, with this list being displayed prominently in large font and the SSBCI disclaimer appearing in very small font at the end of the ad. Often the disclaimer is brief, merely stating that the enrollee must have one of the identified chronic conditions in order to receive the benefit and that eligibility will be determined after enrollment, with no other information provided. A beneficiary reading such an ad could easily miss the small-size disclaimer at the end because their attention is immediately drawn to the long, attractive list of appealing benefits prominently displayed in large, bold font. This type of SSBCI marketing is potentially misleading because, at face value, it might appear to a beneficiary that if they enroll in the advertised plan, they can receive all the highlighted benefits, without any question as to the beneficiary's eligibility, what an eligibility determination entails, or when eligibility is assessed.

Based on our findings, we proposed to expand the current required SSBCI disclaimer to include more specific requirements, with the intention of increasing transparency for beneficiaries and decreasing misleading advertising by MA organizations. Our proposed expansion of the SSBCI disclaimer included a clarification of what must occur for an enrollee to be eligible for the SSBCI. That is, per § 422.102(f), the enrollee must first have the required chronic condition(s), then they must meet the definition of a ''chronically ill enrollee'' at section 1852(a)(3)(D)(iii) of the Act and § 422.102(f)(1)(i)(A), and finally the MA organization must determine that the enrollee is eligible to receive a particular SSBCI under the plan's coverage criteria. (See section IV.C. of this final rule for a more detailed discussion of the requirements for SSBCI.) An MA organization designs and limits its SSBCI to target specific chronic conditions. An enrollee might meet the definition of ''chronically ill enrollee'' but nonetheless be ineligible for the MA organization's advertised SSBCI because they do not have the specific chronic condition(s) required for the particular SSBCI being advertised. Taking these important SSBCI eligibility requirements into account, we proposed to amend the required SSBCI disclaimer content to clearly communicate the eligibility parameters to beneficiaries without misleading them. Specifically, at § 422.2267(e)(34), we proposed three key changes to the regulation and two clarifications.

First, we proposed to redesignate current paragraph (e)(34)(ii) as paragraph (e)(34)(iii) and add a new paragraph (e)(34)(ii), in which we proposed to require MA organizations offering SSBCI to list, in their SSBCI disclaimer, the chronic condition or conditions the enrollee must have to be eligible for the SSBCI offered by the MA organization. Per § 422.102(f)(1)(i)(A), a ''chronically ill enrollee'' must have one or more comorbid and medically complex chronic conditions to be eligible for SSBCI. (See section IV.C. of this final rule for a more detailed discussion of the definition of ''chronically ill enrollee'' and eligibility for SSBCI as part of our finalized provision to strengthen the requirements for how determinations are made that a particular item or service may be offered as SSBCI and eligibility determinations for SSBCI.) We proposed that if the number of condition(s) is five or fewer, then the SSBCI disclaimer must list all condition(s), and if the number of conditions is more than five, then the SSBCI disclaimer must list the top five conditions, as determined by the MA organization. For this top five list, we proposed that the MA organization has discretion to determine the five conditions to include. In making this determination, an MA organization might consider factors such as which conditions are more common or less obscure among the enrollee population the MA organization intends to serve. We explained that five was a reasonable number of conditions for the MA organization to list, so that a beneficiary might have an idea of the types of conditions that might be considered for eligibility for the SSBCI, without listing so many conditions that a beneficiary ignores the information.

Second, we proposed to revise newly redesignated paragraph (e)(34)(iii). Section 422.2267(e)(34)(ii) currently requires that MA organizations that offer SSBCI convey that not all members will qualify. We proposed to expand this provision to require that the MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in § 422.102(f)(1)(i)(A) and on the MA organization's coverage criteria for a specific SSBCI item or service required

[151] *https://content.naic.org/sites/default/files/State%20MA%20Marketing%20Authority%20Senate%20Letter%20.pdf.*

[152] See 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 Final Rule (87 FR 27704), *which appeared in the* ***Federal Register*** on May 9, 2022.

by § 422.102(f)(4). Section 1852(a)(3)(D) of the Act and § 422.102(f) provide that SSBCI are a permissible category of MA supplemental benefits only for a ''chronically ill enrollee,'' as that term is specifically defined, and the item or service must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. In other words, just because an enrollee has one of the conditions listed in the SSBCI disclaimer, it does not automatically mean that the enrollee is eligible to receive the relevant SSBCI, as other criteria will also need to be met. In addition, a particular item or service must meet the requirements in § 422.102(f)(1)(ii) to be offered as an SSBCI. Likewise, as finalized in section IV.C. of this final rule, the requirements for the item or service to be covered as an SSBCI at § 422.102(f) also apply in the sense that an MA organization would also need to meet those requirements to offer SSBCI. Determinations on whether an MA organization may offer coverage of a particular item or service as an SSBCI will generally be made before an MA organization begins marketing or communicating the benefits, therefore, we did not include those requirements for when an MA organization may offer SSBCI in the proposed expansion of the SSBCI disclaimer. Our proposed newly redesignated § 422.2267(e)(34)(iii) referred to the eligibility requirements and MA organization responsibilities in § 422.102(f) because we expected the MA organization to use this information in developing their SSBCI disclaimer to clearly convey that not all enrollees with the required condition(s) will be eligible to receive the SSBCI. Per § 422.102(f) currently and with the revisions finalized in section IV.C. of this final rule, MA organizations offering SSBCI must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

The SSBCI disclaimer is model content, so each MA organization may tailor their disclaimer's language to convey that, in addition to having an eligible chronic condition, the enrollee must also meet other eligibility requirements (*i.e.,* the definition of a ''chronically ill enrollee'' and the coverage criteria of the MA organization for a specific SSBCI item or service) to receive the SSBCI. MA organizations would not need to specifically detail the additional eligibility requirements (such as the coverage criteria) in the disclaimer, but rather convey that coverage is dependent on additional factors, and not only that the enrollee has an eligible chronic condition. For example, an MA organization might use the following language in its SSBCI disclaimer: ''Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility requirements must be met before the benefit is provided. For details, please contact us.'' We are providing this language as an example, as the SSBCI disclaimer is model content. Therefore, in developing their SSBCI disclaimer, MA organizations may deviate from the model so long as they accurately convey the required information and follow CMS's specified order of content, if specified (§ 422.2267(c)). Currently, § 422.2267(e)(34) does not specify the order of content for the SSBCI disclaimer, and we did not propose to add such a requirement; however, MA organizations must accurately convey the required information listed in the regulatory text at § 422.2267(e)(34)(i)–(iii) in their SSBCI disclaimer. In addition, the disclaimer as drafted by the MA organization must be clear, accurate, and comply with all applicable rules on marketing, communications, and the standards for required materials and content at § 422.2267(a).

Third, at new proposed paragraph (e)(34)(iv), we proposed specific formatting requirements for MA organizations' SSBCI disclaimers in ads, related to font and reading pace. These proposed formatting requirements would apply to SSBCI disclaimers in any type of ad, whether marketing or communications. For print ads, we reiterated our existing requirement under paragraph (a)(1) that MA organizations must display the disclaimer in 12-point font, Times New Roman or equivalent. For television, online, social media, radio, or other-voice-based ads, we proposed that MA organizations must either: (1) read the disclaimer at the same pace as the organization does for the phone number or other contact information mentioned in the ad, or (2) display the disclaimer in the same font size as the phone number or other contact information mentioned in the ad. For outdoor advertising (ODA)—which is defined in § 422.2260 and includes billboards—we proposed that MA organizations must display the disclaimer in the same font size as the phone number or other contact information appearing on the billboard or other ODA. The specific font and reading pace requirements for the SSBCI disclaimer in ads would appear at new proposed paragraphs (e)(34)(iv)(A) and (B).

Finally, in revisiting the requirement at § 422.2267(e)(34), we explained that additional clarification of current requirements was appropriate. In the introductory language at paragraph (e)(34), we proposed a minor addition to clarify that the SSBCI disclaimer must be used by MA organizations who offer CMS-approved SSBCI (as specified in § 422.102(f)). Also, we proposed to revise current paragraph (e)(34)(iii) (requiring the MA organization to include the SSBCI disclaimer in the material copy which mentions SSBCI benefits) and move it to new proposed paragraph (v). In this newly redesignated paragraph (v), we proposed to clarify that MA organizations must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We also proposed a slight adjustment in this paragraph to delete the redundant word ''benefits'' after ''SSBCI.''

In summary, we stated in the proposed rule that this proposal would expand upon the current SSBCI disclaimer requirements at § 422.2267(e)(34) in several important ways. Requiring a more robust disclaimer with specific conditions listed would provide beneficiaries with more information to determine whether a particular plan with SSBCI is appropriate for their needs. We explained that the revised disclaimer would diminish the ambiguity of when SSBCI are covered, thus reducing the potential for misleading information or misleading advertising. We also stated that our goal was to ensure that beneficiaries enrolling in MA choose a plan that best meets their health care needs. Transparency and precision in marketing and communications to current and potential enrollees was of utmost importance in our proposal.

We did not score this provision in the COI section since we believe all burden impacts of this provision have already been accounted for under OMB control number 0938–1051 (CMS–10260). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

We solicited comment on this proposal, including on the accuracy of our assumptions regarding information collection requirements and regulatory impact. We did not receive comment on our information collection requirements nor regulatory impact analyses for the proposed revisions to § 422.2267(e)(34) regarding the SSBCI disclaimer. We thank commenters for their input on CMS's proposed amendments to § 422.2267(e)(34). We received the following comments on this proposal, and our response follows:

Comment: The majority of commenters overwhelmingly supported CMS's proposal to strengthen and add more specific requirements to the SSBCI disclaimer in order to decrease misleading advertising and increase transparency for beneficiaries. Many commenters believed that this proposal would enable beneficiaries to make the most informed decision about SSBCI based on their individual health conditions and select the plan that best meets their health care needs. These commenters agreed with CMS that some current SSBCI advertising could give the false impression that these benefits are available to all beneficiaries, which may confuse and mislead beneficiaries into enrolling in an MA plan with benefits they are not actually eligible for. Commenters emphasized the importance of a beneficiary being able to make fully informed choices and the need to decrease misleading marketing and communications. Several commenters noted the importance of the strengthened SSBCI disclaimer requirements to provide more clarity for beneficiaries and supported the language added to the disclaimer, such as the required list of chronic conditions and eligibility restrictions. For example, a commenter agreed that the proposed expansion of the SSBCI disclaimer would clarify what must occur for an enrollee to be eligible for the SSBCI. Another commenter stated that listing the relevant chronic condition(s) the beneficiary must have to be eligible in the marketing and communications materials, as well as adding the caveat that other coverage criteria also apply and may affect eligibility, will help provide more clarity to enrollees, their family members, and enrollment assisters or advisors.

Response: We thank commenters for their support of our proposal to strengthen and expand the SSBCI disclaimer. We appreciate commenters' deeper insight and feedback into the importance of these requirements to both protect beneficiaries from misleading marketing and communications tactics and ensure beneficiaries can make informed health care choices.

Comment: Many commenters offered recommendations for CMS's SSBCI disclaimer proposal. Some commenters suggested that the disclaimer language should be simple, straightforward, and easy to understand, using plain language at an appropriate reading level. A commenter suggested CMS could consider simplifying the disclaimer by using straightforward language to convey eligibility criteria, limitations, and the fact that eligibility does not guarantee benefits. The commenter also suggested CMS could provide a standardized template, language format, or utilize visual aids or bullet points to make the information more digestible and easier for a beneficiary to navigate. There was a recommendation to test the communication with beneficiaries. Another commenter appreciated the detailed benefit description but recommended refining the language to ensure clarity and ease of understanding for beneficiaries of varying literacy levels, promoting inclusive communication. A commenter suggested that CMS consult health literacy experts in the creation of SSBCI disclaimers.

Response: We thank commenters for providing recommendations on how to ensure the updated SSBCI disclaimer is clear and easy for beneficiaries to understand given that the intent of our proposal is to ensure beneficiaries are clearly informed about their options. At the same time, we are aware and concerned about the many marketing and communications materials that mention SSBCI, but do not clearly communicate that beneficiaries have to meet certain criteria to be eligible for those benefits. Specifically, SSBCI are available to a small number of individuals that must meet specific eligibility criteria. As per section 1852(a)(3)(D) of the Act and § 422.102(f), the specific benefit must be within the scope of the definition of SSBCI, including that the benefit be reasonably expected to improve or maintain the health or overall function of the chronically ill enrollee; the enrollee must first have the required chronic condition(s); the enrollee must meet the definition of a ''chronically ill enrollee'' at § 422.102(f)(1)(i)(A); and finally the MA organization must determine that the enrollee is eligible to receive the particular SSBCI under the plan's coverage criteria for the specific SSBCI. To accurately advertise these benefits, MA organizations must make beneficiaries aware that certain eligibility criteria are used to determine who can receive SSBCI. A significant way to further this purpose is the SSBCI disclaimer. As such, it is important that this disclaimer thoroughly conveys all pertinent eligibility information that a beneficiary needs to determine whether they might be able to access the SSBCI. While the revisions and additions to the disclaimer that we proposed and are finalizing in this rule may be more substantial than before, we strongly believe that the benefits of the disclaimer outweigh any potential risks raised by commenters.

We reiterate that the SSBCI disclaimer, currently and as revised in this rule, is model content, and MA organizations are not required to conform with a standardized template or model format provided by CMS, so long as the MA organization's materials accurately convey the required materials' vital information.

However, as provided earlier, some example SSBCI disclaimer language that MA organizations might use includes, ''Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility requirements must be met before the benefit is provided. For details, please contact us.'' We believe this example language is clear and simple. To address commenters' concerns about using simple, straightforward, and plain language, we offer here another example of some SSBCI disclaimer language that MA organizations might use: ''Eligibility is determined by whether you have a chronic condition associated with this benefit. Standards may vary for each benefit. Contact us to confirm your eligibility for these benefits.'' Again, we believe this additional example language is clear and easy to understand, which is vital to allowing beneficiaries to make informed health care decisions. We note that these examples of SSBCI disclaimer language capture only the requirements at § 422.2267(e)(34)(iii) and not paragraphs (e)(34)(i) or (ii). In addition to the information required at paragraph (e)(34)(iii), MA organizations must also provide the list of chronic conditions as required by paragraph (e)(34)(ii) as finalized.

MA organizations may decide how to present the SSBCI disclaimer and make the information within it more digestible so long as the content and formatting requirements in § 422.2267(e)(34), as finalized, are met. There is nothing precluding MA organizations from using visual aids or bullet points, provided they comply with the minimum requirements at § 422.2267(e)(34) as finalized. Regarding the comment recommending CMS test the communication with beneficiaries, we appreciate this recommendation and will take it under consideration for the future. We agree with commenters that the SSBCI disclaimer language should be clear for varying literacy levels, and we encourage MA organizations to consider these things as they develop their own unique disclaimers. We also encourage MA organizations to consult with health literacy experts as necessary to ensure the information contained in their SSBCI disclaimers is accessible and inclusive for all beneficiaries.

Comment: Some commenters expressed concern about the SSBCI disclaimer length, arguing that lengthy disclaimer language might cloud helpful information that was meant to increase beneficiary education of available benefits. These commenters were also concerned that the added language may have the unintended effect of discouraging beneficiaries from reaching out to access SSBCI services. A commenter explained that, as disclaimers get longer, more complicated, and less individualized, there is a greater risk that they are ignored, misunderstood, or dissuade a beneficiary from selecting an MA plan. A few commenters were concerned that the SSBCI disclaimer may get lost amidst other required CMS disclaimers and further confuse beneficiaries.

Response: We appreciate the points commenters raised about the SSBCI disclaimer length and the possibility that added language may discourage beneficiaries from reaching out to access SSBCI services. However, we believe that the SSBCI disclaimer can be said succinctly as long as all the requirements at § 422.2267(e)(34) are met and the eligibility restrictions are clear and accurate. We do not agree with commenters that the added language may discourage beneficiaries from reaching out to access SSBCI services. Instead, since SSBCI have limited eligibility, the added language would enable beneficiaries to have a clearer understanding of whether they may even be eligible for the advertised SSBCI. We are prioritizing this change to the SSBCI disclaimer because it is essential that beneficiaries have the information they need in order to select the plan that best meets their health care needs. If a beneficiary is interested in an advertised benefit, we believe that the SSBCI eligibility criteria are key information for beneficiaries to make an informed choice. The purpose of the disclaimer is to ensure that a beneficiary does not base their decision to sign up for a plan on advertised SSBCI for which the beneficiary turns out to be ineligible. This type of marketing and communications is potentially misleading and confusing to beneficiaries and could be out of compliance with CMS regulations. We believe transparently advertised SSBCI, accompanied by disclaimers that meet the revised requirements at § 422.2267(e)(34) finalized here, will help to ensure beneficiaries have the information they need to make health care choices that best fit their needs. Moreover, we again stress our belief that the benefits outweigh any potential risks raised by commenters.

Comment: Many commenters expressed their support for CMS's proposed formatting requirements for the SSBCI disclaimer. A commenter noted that listing the specific chronic condition in the same format, whether it be read at the same speed or displayed in the same font size, as the phone number listed in the ad, will better inform beneficiaries in making the right decision. Another commenter added that they appreciated the proposal that the disclaimer cannot be in smaller font than other key text in print communications and must be read at a comparable speed to other plan information for radio/television ads. They further added that SSBCI and other supplemental benefits continue to be a draw for beneficiaries, so this effort will help ensure that they are not misled about which benefits might be available to them. A commenter believed the additional formatting requirements are appropriate for the older adult population and indicated that the current SSBCI disclaimer information was not easy for beneficiaries to understand.

Response: We thank commenters for expressing their support for the formatting requirements we proposed for the SSBCI disclaimer. We wish to ensure that in every marketing and communications advertising modality, beneficiaries can read or hear and clearly understand the disclaimer and be informed about SSBCI and the specific eligibility criteria.

Comment: A few commenters voiced concerns about CMS's proposed formatting requirements for the SSBCI disclaimer. A few commenters were concerned that there would not be enough ad space for the full SSBCI disclaimer, and that the disclaimer could be longer than the ad itself. A commenter argued that due to the disclaimer length and font size, it could potentially fill the page or ad to where a beneficiary might become disinterested or confused with too much information. The commenter added that due to limited space on such ads, MA organizations may be deterred from promoting SSBCI that could provide beneficiaries with what they possibly need. A commenter also stated that the disclaimer accounts for almost 30 seconds of a radio ad, which is an important media avenue for the target population, and thus more CMS disclaimer requirements might be difficult to achieve due to media limitations. A few commenters recommended CMS work with MA organizations on communication standards, such as font size or disclaimer presentation, to ensure the ad modality is considered, giving specific suggestions for modalities such as social media ads, television commercials, out-of-home signs, search ads, and verbal ads like radio or streaming audio. Commenters suggested that for certain digital or offline modalities with limited space, CMS should permit a link to the disclaimer via a URL weblink or a QR code that would direct beneficiaries to the full SSBCI disclaimer elsewhere. A commenter noted that character counts and content limits enforced by some website owners create additional barriers to adding SSBCI disclaimer language. These commenters generally recommended that CMS adopt more flexible requirements or explicit exceptions for certain modalities that offer limited text display or are of short display duration, like banner ads, other online or television ads, and billboards.

Response: We understand some commenters are concerned about the formatting requirements and how much space the SSBCI disclaimer might take up on a given marketing or communications ad. Our priority, however, is to ensure that SSBCI ads are not misleading or confusing for beneficiaries. Ensuring that beneficiaries have the information they need to make an informed choice is a paramount consideration, and the SSBCI disclaimer requirements adopted in this rule further that goal. Each MA organization's approach to ads is a business decision that depends, in part, on their marketing and communications strategy. Importantly, all aspects of our new SSBCI disclaimer requirements should be significant factors in the MA organization's decision-making process, in conjunction with any potential ad space limitations or other ad roadblocks. It is vital that beneficiaries have all the information necessary to select the plan that best meets their health care needs. If a beneficiary is interested in an advertised benefit, we believe that the SSBCI eligibility criteria are important for beneficiaries to make an informed choice, as they would not be able to access that benefit if they are ineligible. Without the SSBCI disclaimer, the beneficiary might end up enrolling in a plan only to find out that they cannot access the SSBCI, and it is possible that they, due to lacking the information necessary to make an informed enrollment choice, may have sacrificed other enrollment opportunities for the ability to access those advertised SSBCI. SSBCI are not benefits that everyone can access, so it should be clear that when

such a benefit is advertised, these benefits are not guaranteed unless specific eligibility criteria are met.

We disagree with commenters that there should be a separate link for the full SSBCI disclaimer and are finalizing the formatting requirements as proposed. The disclaimer needs to be on the ad itself because a link would not make it clear to the beneficiary that there are specific chronic conditions and other eligibility requirements associated with being able to access a particular advertised SSBCI. The SSBCI disclaimer ensures that beneficiaries are immediately aware of the eligibility criteria for an advertised SSBCI and can make informed decisions about their health care coverage options. From a beneficiary's perspective, linking elsewhere would not make the information clear and more accessible, but would instead lead to an unnecessary delay in the amount of time it takes for the beneficiary to receive the information by adding a burdensome extra step of clicking on a link or QR code. Realistically, most beneficiaries would probably not click on such a link. Regarding character limits or any other text limitations in a specific modality, if the disclaimer does not fit, then it is likely not the most suitable modality for an SSBCI marketing ad given the nature of these benefits and nuances that are necessary for a beneficiary to make an informed choice when considering SSBCI. Our requirement is that the disclaimer must be included in all marketing and communications materials that mention SSBCI and must follow all content requirements as specified in the finalized regulatory text. If an ad mentions an SSBCI without the required disclaimer, then it is out of compliance with CMS rules.

Comment: A few commenters communicated support for CMS's proposal to require the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. Other commenters were unclear as to whether the disclaimer should apply to all communications or only for pre-enrollment activity, rather than post-enrollment communications. A commenter noted that for post-enrollment communications, an enrollee would have already been notified they meet the necessary qualifications for the benefit and would have already been receiving educational material on the benefit, so the addition of the SSBCI disclaimer would create confusion. The commenter also expressed concerns about differences between VBID and SSBCI disclaimer requirements and that this could further confuse beneficiaries.

Response: We thank commenters for their support of our requirement that the SSBCI disclaimer be present in all marketing and communications materials that mention SSBCI. As finalized in § 422.2267(e)(34), the SSBCI disclaimer must appear in all communications materials produced by MA organizations, including both pre-enrollment and post-enrollment communications materials that mention SSBCI. We disagree with the commenter's sentiment that including the disclaimer on post-enrollment communications materials would confuse the enrollee. Even if an enrollee has already been notified that they meet the SSBCI qualifications, we do not believe there would be any harm or risk in including the disclaimer on a potential post-enrollment educational communications material for that enrollee. The enrollee could simply disregard the disclaimer since they already know that they qualify for the benefit. Moreover, we believe the likelihood of an MA organization sending post-enrollment communications materials on SSBCI to enrollees whom the MA organization has already notified that they qualify for the benefits is low because those enrollees would likely not need to be educated further on these benefits, but instead would probably be ready to utilize the benefits.

Regarding the comment about differences between VBID and SSBCI disclaimer requirements and potential beneficiary confusion, we note that the VBID model is administered under section 1115A of the Act, and there is authority to waive certain program requirements if necessary to test the payment or service model; we refer readers to the web page for the VBID model at: *https://www.cms.gov/priorities/innovation/innovation-models/vbid* for more information about the model and its requirements. Due to the nature of the VBID model and the flexibilities in benefits available under that model, there are specific marketing and communications requirements applicable to model participants. Given SSBCI and VBID benefits are different benefits with different requirements, both disclaimers are necessary.

Comment: A few commenters were concerned that the chronic conditions list would be difficult for MA organizations to implement and that it could lead to beneficiary confusion. Some commenters were worried it could get confusing for MA organizations to explain in an SSBCI disclaimer the chronic conditions that apply to the specific benefits listed or promoted in an ad. A commenter believed it was unclear how CMS intended MA organizations to proceed when an ad includes multiple SSBCI, for which there might be varying eligibility criteria or condition requirements. Another commenter added that for an MA organization offering multiple SSBCIs, the disclaimer, as worded, might result in an overly long and complex disclaimer, and most prospective enrollees would not read or understand it. Some commenters had concerns about how to implement the list of top five chronic conditions and how that list might impact beneficiaries, and requested CMS further clarify their expectations. These commenters requested CMS clarify that the SSBCI disclaimer needs to identify up to five chronic conditions for which one or more SSBCI may be available, rather than specifying up to five chronic conditions for each individual SSBCI, which may be lengthy. A few commenters were concerned that by listing only five conditions for an SSBCI, enrollees with eligible conditions not listed may inadvertently believe that they are not eligible for the SSBCI because it gives the impression that the five conditions listed are the only ones covered.

Response: We agree with commenters that some clarification of the requirements for the chronic conditions list in the SSBCI disclaimer is needed. We recognize that an MA organization may include more than one type of SSBCI in its marketing or communications material. Consequently, there is a strong possibility that each type of SSBCI may have different eligible chronic conditions or there may be some overlap because some chronic conditions apply to more than one type of SSBCI mentioned in the material. There is also the possibility that an MA organization may have multiple plans with different SSBCI, and consequently may choose to either advertise the SSBCI specific to each plan or advertise SSBCI for all plans generally. After considering these nuances, we acknowledge that there are many different potential scenarios for how MA organizations might advertise SSBCI and use their SSBCI disclaimer to associate the listed chronic conditions with the types of SSBCI mentioned. We are therefore finalizing § 422.2267(e)(34)(ii) with revisions compared to our proposal in the November 2023 proposed rule, as follows.

First, we are changing the reference in paragraph (e)(34)(ii) from ''MA organization'' to ''applicable MA plan(s)'' to clarify that the SSBCI the MA organization advertises must be

clearly tied to the applicable MA plan or plans that offer that SSBCI. For similar reasons, we are finalizing paragraph (e)(34)(iii) with a modification that clarifies that the disclaimer used by the MA organization must communicate that coverage depends on the enrollee being a ''chronically ill enrollee'' and on ''the applicable MA plan's coverage criteria'' for a specific SSBCI. Therefore, if an MA organization is advertising SSBCI for all of the MA organization's plans that offer SSBCI, and there are differences between those plans in terms of the types of SSBCI and types of chronic conditions the enrollee must have to be eligible for the SSBCI, then the MA organization must make those differences explicitly clear.

Next, we are clarifying the requirements for the chronic conditions list in the SSBCI disclaimer by outlining several different scenarios and the requirements associated with each. Specifically, we are finalizing the regulation text with revisions to address: (1) when only one type of SSBCI is mentioned, and (2) when multiple types of SSBCI are mentioned. When only one type of SSBCI is mentioned, the regulation addresses two scenarios: (1) If the number of condition(s) is five or fewer, then the MA organization must list all condition(s); and (2) If the number of conditions is more than five, then the MA organization must list the top five conditions (as determined by the MA organization). When multiple types of SSBCI are mentioned, the regulation addresses two scenarios: (1) If the number of condition(s) is five or fewer, then the MA organization must list all condition(s), and if relevant, state that these condition(s) may not apply to all types of SSBCI mentioned; and (2) If the number of condition(s) is more than five, then the MA organization must list the top five conditions (as determined by the MA organization) for which one or more listed SSBCI is available.

We believe that making these modifications to clearly outline the different scenarios achieves the goal of limiting ambiguity for MA organizations, while simultaneously preserving our intention to ensure that SSBCI marketing and communications is transparent and not misleading for beneficiaries. Additionally, we believe an alternate approach of tying each listed chronic condition to each type of SSBCI mentioned would have been overly burdensome and resulted in a long, complex SSBCI disclaimer. Lastly, we would like to address the comment that listing only five chronic conditions may inadvertently lead enrollees with eligible conditions not listed to believe that they are not eligible for the SSBCI because it may give the impression that the five conditions listed are the only ones that are eligible. We agree that this is a valid concern, therefore, we are finalizing § 422.2267(e)(34)(ii) with a revision which requires that, in instances where the MA organization lists the top five conditions, but there are more than five conditions that may be eligible for the benefit, MA organizations must convey that there are other eligible conditions not listed. We believe that all these modifications are responsive to comments and further strengthen and clarify our SSBCI disclaimer requirements.

Comment: A commenter was worried about giving deference to MA organizations to choose the top five conditions they will list, suggesting CMS use a metric for MA organization determinations on what conditions would constitute such a ''top five,'' or, in the alternative, that the MA organization be required to list all the applicable conditions. A different commenter had a similar request with concerns that if CMS were to finalize this amendment as proposed, then MA organizations could select conditions in a way that increases racial health disparities (such as by omitting sickle cell anemia from the list).

Response: We acknowledge the commenter's concern about giving deference to MA organizations to choose the top five conditions they will list. However, we are finalizing our proposal to allow the MA organization's discretion as to which top five conditions to include because we believe the MA organization is best positioned to make this determination since they are most familiar with their own SSBCI and corresponding eligibility and coverage criteria. Regarding the suggestion for CMS to use a metric for MA organizations to determine whether a specific qualifying condition is one of the top five conditions, we remind commenters that in the proposed rule, we provided some factors that an MA organization might consider, such as which conditions are more common or less obscure among the enrollee population the MA organization intends to serve. Other approaches an MA organization might take are to list the top five conditions that are most prevalent in the service area of the MA plan offering the SSBCI, or to list the top five conditions that are used most commonly in determining eligibility for the SSBCI. We believe these examples are sufficient and defer to MA organizations to make their own decisions on their chosen top five conditions using these considerations so long as there is a reasonable explanation for why the selected conditions are the ''top five'' using a reasonable interpretation of the regulation. We believe that the MA organization should not be required to list all applicable chronic conditions because, as stated previously, a beneficiary may ignore the information if many conditions are listed.

Regarding the concern about MA organizations potentially selecting conditions in a way that increases racial health disparities, we note that MA organizations are subject to anti-discrimination provisions under 45 CFR Part 92. Therefore, an MA organization that is found to be deliberately selecting chronic conditions for the list in their SSBCI disclaimer in a discriminatory manner, including a racially discriminatory manner, may face compliance action.

Comment: Some commenters worried that CMS's proposed new requirements for the SSBCI disclaimer would make SSBCI less accessible to beneficiaries because they might think they are ineligible if they do not see their chronic condition listed. Regarding the disclaimer content, another commenter stated that they believed this change might be confusing to beneficiaries who may not know if they meet the § 422.102(f)(1)(i)(A) definition of ''chronically ill enrollee.'' They instead recommended that the standard for eligibility be simple to understand, such as, if a beneficiary has an eligible chronic condition, then they will be eligible for the benefit.

Response: We agree with commenters' concerns that if a beneficiary does not see their chronic condition listed in the SSBCI disclaimer, then they might think they are ineligible for the benefit. Therefore, we are finalizing § 422.2267(e)(34)(ii) with changes to require the MA organization, where relevant, to state in its disclaimer that there may be other eligible chronic conditions that are not listed. We believe this will decrease the likelihood of beneficiaries assuming they cannot access SSBCI if their chronic condition is not listed in the disclaimer.

Regarding comments about the disclaimer content (specifically proposed § 422.2267(e)(34)(iii)) being potentially confusing to beneficiaries, we clarify here that MA organizations should not cite the CMS regulatory definition of ''chronically ill enrollee'' in their actual SSBCI disclaimer, as this would not make sense to beneficiaries. In addition, MA organizations must not simply state that if a beneficiary has an eligible chronic condition, then they

will be eligible for the benefit because this is not accurate. Rather, as noted in the proposed rule, each MA organization may tailor their disclaimer's language to convey that, in addition to having an eligible chronic condition, the enrollee must also meet other eligibility requirements to receive the SSBCI. In the proposed rule and in a previous response to a comment, we offered some example language to this effect that an MA organization might use in its disclaimer. To reiterate, the SSBCI disclaimer is model content, therefore, MA organizations may deviate from the model so long as they accurately convey the required regulatory information in their disclaimer. As previously stated, we encourage MA organizations to use simple and easy to understand disclaimers written in plain language. The policy we proposed and are finalizing is that the SSBCI disclaimer must convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the listed SSBCI because coverage of the item or service depends on the enrollee meeting other eligibility and coverage criteria.

Comment: A few commenters opposed our proposal, claiming that the disclaimer is not the right approach or not the most effective way to address misleading SSBCI marketing and communications. Commenters expressed support for increasing the transparency of available supplemental benefits that beneficiaries are eligible to utilize but disagreed that additional disclaimer requirements are an effective way to do this. A commenter expressed concern that the additional SSBCI disclaimer requirements would not truly address CMS's concerns with deceptive marketing and communications practices by bad actors. Some commenters recommended CMS withdraw the proposal and not change the current SSBCI disclaimer requirements, which they claimed are more streamlined than the proposed disclaimer. A commenter stated that the longer and more complicated the disclaimers get, the less effective they become. Another commenter suggested CMS withdraw the proposal and work with stakeholders to determine a more effective strategy whereby SSBCI transparency for beneficiaries can be meaningfully improved. A commenter noted their beneficiary complaint tracking suggests that disclaimers are not as effective as direct communication with sales representatives, agents and brokers, and customer service representatives. The commenter expressed the critical role agents and brokers play in explaining the types of supplemental benefits, eligibility requirements, access, and other critical information that can be distilled down from the disclaimers in an easy-to-understand format tailored for each beneficiary.

Response: We understand that some commenters are not fully supportive of this policy for various reasons, however, we have decided to finalize our proposal with slight modifications. While we recognize that there may be a range of different approaches to solve the problems we have historically observed in SSBCI marketing and communications, in formulating our proposal, we have decided that strengthening the SSBCI disclaimer was an effective option to address misleading and non-transparent SSBCI marketing and communications. We have received numerous complaints and concerns from a variety of sources, such as beneficiaries, advocacy groups, and State Health Insurance Programs, about the draw of these benefits and the harm caused when insufficient information about these benefits leads a beneficiary to enroll in an MA plan that does not meet their health care needs. These instances have led to beneficiaries enrolling in plans because they were lured by ads mentioning these special benefits only to discover that they are ineligible for the advertised SSBCI. We believe that the strengthened SSBCI disclaimer could decrease confusing or potentially deceptive marketing and communications practices as it is clearer and more comprehensive than the current disclaimer. We believe this is in fact the right approach and will be effective in delivering SSBCI marketing and communications messaging to beneficiaries in a clear, transparent way that is not misleading or confusing.

Therefore, we decline commenters' suggestions to withdraw this proposal. We note that we will continue to provide guidance to MA organizations and answer questions about the requirements for the SSBCI disclaimer and compliance with our other regulatory requirements. Lastly, we agree with commenters that agents and brokers, sales representatives, and customer service representatives play a critical role in communicating with beneficiaries and explaining SSBCI in a way that is easy for beneficiaries to understand.

Comment: A few commenters believed CMS's proposed changes to the SSBCI disclaimer requirements may confuse or mislead dually eligible individuals. A commenter argued that some dually eligible individuals, in response to SSBCI advertising or communications, may choose an MA plan to receive some limited additional benefits that are unavailable under traditional Medicare; the commenter expressed concern that such individuals may make this enrollment choice because they are unaware that as dually eligible individuals they can access some of the same benefits through a Medicaid program. The commenter stated that the SSBCI disclaimer language should be amended to transparently advise potential enrollees what they may be giving up by choosing one of these MA plans, as many dually eligible individuals are misled into choosing an MA plan based on the extra benefits, when they may already be eligible for such benefits under Medicaid. Another commenter urged CMS to prohibit misleading marketing and communications of SSBCI that duplicate Medicaid benefits, arguing that advocates report that many dually eligible individuals are lured by these ads and report not understanding the limits of the extra benefits or restrictions. The commenter requested more robust SSBCI disclaimer language than contemplated by this rule. Another commenter suggested that CMS should require D–SNPs specifically to indicate (through their SSBCI disclaimer, on all plan marketing, and communications materials, and in the EOC) which benefits are also available through Medicaid, to reduce misleading marketing and communications of SSBCI that duplicate Medicaid benefits. The commenter believed that this would not be an unduly burdensome requirement because D–SNPs already tailor each plan's information to a particular state and frequently advertise benefits to which dually eligible individuals are already entitled to receive more comprehensively in both duration and scope under Medicaid.

Response: We understand commenters' concerns regarding the potential for misleading marketing and communications of SSBCI that duplicate Medicaid benefits. This is an important consideration, and we appreciate commenters raising the issue. CMS is committed to protecting all beneficiaries, including dually eligible individuals, from confusing and potentially misleading marketing and communications practices, while also ensuring that they have accurate and necessary information to make coverage choices that best meet their health care needs. While we are not including SSBCI disclaimer language specifically for dually eligible individuals or D–

SNPs, we do want to clarify our existing authority related to MA marketing.

Sections 1851(h) and 1852(j) of the Act provide CMS with the authority to review marketing rules, develop marketing standards, and ensure that marketing materials are accurate and not misleading. Additionally, these provisions provide CMS with the authority to prohibit certain marketing activities conducted by MA organizations and, when applicable, agents, brokers, and other third parties representing these organizations. Pursuant to section 1851(h)(1) and (2) of the Act and CMS's implementing regulations, MA organizations may not distribute any marketing material to MA-eligible individuals (including dually eligible individuals, when applicable) unless the material has been submitted to CMS for review and CMS has not disapproved such material. CMS's regulations at § 422.2262 provide, among other things, that MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees, or engage in activities that could misrepresent the MA organization. Section 422.2262 applies to all MA communications and marketing materials, including advertising on behalf of MA organizations. In accordance with regulations at § 422.2261, MA organizations must submit all marketing materials for CMS review and may not distribute or otherwise make available any marketing materials unless CMS has reviewed and approved the material, the material has been deemed approved, or the material has been accepted via CMS's File and Use process. Additionally, CMS routinely monitors MA marketing materials and may take compliance action if we determine that an MA organization is out of compliance with our rules. Considering the existing authority CMS has for oversight and enforcement, we believe this is sufficient to address commenters' concerns regarding dually eligible individuals and the SSBCI disclaimer.

We expect and require MA organizations whose audience may include dually eligible individuals to craft their ads and their SSBCI disclaimers in a way that is accurate and not misleading or confusing, in accordance with CMS rules. We recognize that partial-benefit dually eligible individuals and full-benefit dually eligible individuals have different levels of access to Medicaid benefits. For example, while full-benefit dually eligible individuals would generally have access to non-emergency transportation (NEMT) through their Medicaid coverage, partial-benefit dually eligible individuals generally would not. An MA organization advertising SSBCI that include NEMT would offer a new benefit for partial-benefit dually eligible individuals, but the NEMT generally would not be a new benefit for full-benefit dually eligible individuals. Given that both categories of dually eligible individuals may enroll in almost any non-SNP, it does not seem practical for MA organizations to tailor the SSBCI disclaimer in a way that describes which SSBCI would be covered under Medicaid, depending on the eligibility category of the dually eligible individual. In some states, Medicaid benefits may be limited to certain waiver participants or only covered in specific situations. At this time, we will not be modifying the SSBCI disclaimer further, but we understand commenters' concerns and will consider this for future rulemaking.

Comment: A commenter suggested that the actual SSBCI eligibility criteria must be available in the MA organization's existing plan materials (such as the Evidence of Coverage (EOC), Summary of Benefits (SB), and plan website) and that the SSBCI disclaimer should tell the beneficiary how they can obtain these eligibility criteria and hyperlink to them from any online reference.

Response: To the extent that the materials noted by the commenter already contain the same (or more detailed) content as required in the SSBCI disclaimer in a manner that achieves the same purpose, CMS would consider the MA organizations producing these materials compliant with § 422.2267(e)(34) as finalized, for purposes of the disclaimer content. Thus, in these cases, there is no need for the MA organization to add redundant information to these materials in the form of an SSBCI disclaimer because the required information is already present, and in some cases more detailed, for the beneficiary. This would be the case, for example, in the EOC, an important plan material where covered benefits are described. We note that the EOC is a standardized communications material, meaning that, per § 422.2267(b), it must be used in the form and manner provided by CMS without alteration, aside from a few exceptions. In chapter 4, section 2 (Medical Benefits Chart) of the current 2024 EOC standardized document, CMS requires MA organizations offering SSBCI to include all applicable chronic conditions, information regarding the process and/or criteria for determining eligibility for SSBCI, the actual CMS-approved benefits, and the applicable copays, coinsurance, and deductible for the SSBCI. Per § 422.111(b)(2), (b)(6), and (f)(9), MA organizations are required to disclose in the EOC the benefits offered under a plan, including applicable conditions and limitations, any other conditions associated with the receipt or use of benefits, any mandatory or optional supplemental benefits, and the terms and conditions for those supplemental benefits.

CMS disagrees with the commenter that the disclaimer should also include details about how a beneficiary can obtain the specific SSBCI eligibility criteria used by the MA organization. We agree that the potential eligibility criteria restrictions should be transparent and straightforward for beneficiaries, but the disclaimer is model content that is intended to ensure beneficiaries are aware that there are eligibility criteria and to understand some of the eligible conditions that apply. This will ensure beneficiaries are informed that there are SSBCI restrictions and to notify the beneficiary that they may inquire further with the MA organization about the details of these restrictions if they so choose. We would also like to clarify that the disclaimer is meant to be easy to read and understand, and to quickly alert beneficiaries that they may not be eligible for certain listed benefits. Adding additional information or a hyperlink would further lengthen the disclaimer, so we are not requiring that. We are also not prohibiting MA organizations from electing to provide additional information not required by § 422.2267(e)(34) as finalized in this rule. There are ways that MA organizations can help guide beneficiaries in their SSBCI education. As mentioned earlier, an MA organization can encourage a beneficiary to reach out to them, using simple language such as, ''For details, please contact us'' which would offer beneficiaries an easy and straightforward way to learn more about whether they are eligible for a specific SSBCI. The SSBCI disclaimer requirements, as finalized, are designed to ensure that beneficiaries are immediately aware that SSBCI is not a guaranteed benefit, and they may inquire further with the MA organization if they want to learn more about the eligibility restrictions.

Comment: Another commenter requested that CMS clarify that there will be an exception for marketing and communications materials that do not currently require the Federal Contracting Statement, such as social media, SMS text messages, outdoor ads, banners, and envelopes.

Response: As finalized, there will not be an exception to the SSBCI disclaimer requirement for marketing and communications materials that do not currently require the Federal Contracting Statement. The intent of the disclaimer is to ensure that any place where SSBCI is mentioned, beneficiaries are fully aware that eligibility restrictions apply so that they can make informed health care choices. We believe that the marketing and communications modalities such as those listed by the commenter are modalities where beneficiaries tend to be most at risk of being misled by SSBCI ads and where the content appears to offer benefits that a beneficiary wants and suggests they can easily access or receive by enrolling in the plan. If the beneficiary is unaware that there is a chance they may not qualify, then they may unwittingly sign up for the plan because of benefits that they will not ultimately be able to receive. The exceptions for the Federal Contracting Statement are relevant to that specific provision only and do not apply to the SSBCI disclaimer as finalized here.

Comment: A commenter remarked that ODA are inclusive of billboards and bus shelter ads, which are often read by motorists. The commenter believed imposing new requirements for ODA decreases legibility, impact, and potential safety and requested that CMS allow SSBCI ads to have varying disclaimer requirements based on the ODA medium.

Response: We thank commenters for sharing their concerns about safety for motorists when it comes to including the SSBCI disclaimer on ODA. We agree that these are important considerations for MA organizations when making SSBCI advertising decisions. It is the MA organization's discretion regarding where to advertise SSBCI. If an MA organization has concerns regarding legibility, impact, and potential safety when it comes to including the SSBCI disclaimer on a particular ODA, then they may wish to reconsider their pursuit of that ad modality for SSBCI. MA organizations have ample choice in how they choose to advertise, however, they must comply with our SSBCI disclaimer requirements, including ODA formatting requirements.

Comment: Other commenters encouraged CMS to make the SSBCI disclaimer's model language even clearer by explicitly stating that not everyone who has Medicare is eligible for the benefit and explaining how enrollment in an MA plan differs from traditional Medicare. A commenter suggested that the SSBCI disclaimer should include information about the trade-offs between MA and traditional Medicare and describe potential hurdles in MA, for example, provider networks, utilization management, and prior authorization.

Response: We believe the SSBCI disclaimer requirements, as finalized, do already make it clear that not everyone who has Medicare is eligible for the SSBCI, as MA organizations are required to note SSBCI eligibility restrictions in the disclaimer. Regarding comments recommending that the disclaimer explain the differences between MA and traditional Medicare, we disagree and believe this would not be appropriate nor align with the core purpose of the SSBCI disclaimer. CMS does not require MA organizations to include information about the trade-offs or any comparison between MA and traditional Medicare in their marketing and communications materials, and we are not establishing such a requirement for the SSBCI disclaimer. However, we note that per § 422.2262, CMS does require MA organizations to provide materially accurate information to current or potential enrollees. Therefore, MA organizations must provide accurate information about provider networks, utilization management, and prior authorization wherever MA organizations choose to include such information in their marketing and communications materials.

Comment: Some commenters recommended CMS ensure proper enforcement against misleading SSBCI marketing and communications tactics. One commenter urged CMS to impose high penalties on MA organizations that fail to comply with all the revised marketing and communications requirements for the MA program and that such enforcement action should include civil monetary penalties, suspensions, and for the most abusive actors, permanent bans from MA program participation. Another commenter noted that the current procedures for enforcement of marketing and communications regulations that CMS has in place are not working, and marketing and communications practices that are confusing and misleading to seniors need to stop.

Response: We thank commenters for raising the important topic of enforcement against misleading marketing and communications in general, and we want to assure commenters that CMS takes its enforcement efforts seriously, especially as they relate to the SSBCI disclaimer requirements, as finalized. Accordingly, we would like to provide an overview of our approach to MA enforcement.

CMS engages in various enforcement efforts across the MA program to help ensure the health and wellbeing of MA enrollees. The Office of Program Operations and Local Engagement (OPOLE) routinely monitors MA organizations, with dedicated CMS account managers across ten regions of the country assigned to each MA organization. CMS also maintains MA organization marketing monitoring projects which consist, as provided in § 422.2261, of reviewing and approving (if in accordance with CMS regulations) marketing materials produced by MA organizations and their TPMOs.

Through routine oversight and monitoring, CMS may take compliance actions if it determines that an MA organization is out of compliance with the terms of its contract with CMS. Based on an assessment of the circumstances surrounding non-compliance, CMS may issue a compliance action such as a notice of non-compliance, warning letter, or corrective action plan. As described in § 422.504(m)(3), a notice of non-compliance may be issued for any failure to comply with the requirements of the MA organization's current or prior contract with CMS; a warning letter may be issued for serious and/or continued non-compliance with the MA organization's current or prior contract with CMS; and a corrective action plan may be issued for repeated, not corrected, or particularly serious non-compliance. CMS's criteria for issuing a compliance action depends on six key factors listed at § 422.504(m)(2).

In addition to account management, routine monitoring efforts, auditing, and compliance actions, CMS also has the authority to impose financial penalties, marketing and enrollment sanctions, or contract terminations against MA organizations whose non-compliance meets certain statutory thresholds. CMS evaluates circumstances of documented non-compliance against those thresholds in determining an appropriate action. In circumstances when non-compliance by an MA organization is pervasive, ongoing, and may require significant time and resources to identify and correct, CMS might require a corrective action plan or, if the statutory threshold for non-compliance is met, impose enrollment and marketing sanctions in an effort to protect additional beneficiaries from enrolling in the plan until the MA organization can demonstrate that their issues have been sufficiently corrected and no longer likely to recur. If, however, it is determined that an MA organization's non-compliance has already been corrected by the time it

was identified through CMS's oversight and enforcement efforts, and enrollees or prospective enrollees are no longer in danger of experiencing inappropriate delays or denials to their benefits, a civil money penalty might be the most appropriate response if the non-compliance met statutory standards. If standards for a financial penalty are not met, CMS may still issue a notice of non-compliance which will count against the MA organization during CMS's annual review of their past performance.

In summary, we believe that the above outlined procedures for enforcement of marketing regulations that CMS currently has in place are appropriate and effective. We are confident that these procedures will sufficiently address any potential non-compliance with the SSBCI disclaimer rule by MA organizations.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulation. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are amending § 422.2267(e)(34) largely as proposed, but with modifications. We are finalizing paragraph (e)(34)(ii) with revisions to adopt more specific requirements for when and how an MA organization must list up to five chronic conditions used to determine eligibility for SSBCI identified in marketing and communications materials. These requirements specify how an MA organization must structure its list of chronic conditions in the SSBCI disclaimer when only one type of SSBCI is mentioned and when multiple types of SSBCI are mentioned. Modifications in paragraph (e)(34)(ii) also include changing ''MA organization'' to ''applicable MA plan'' and requiring, where there are more than five eligible conditions, a note indicating that there are other eligible conditions not listed. We are finalizing paragraph (e)(34)(iii) with modifications to ensure that the specific coverage criteria of the MA plan that offers the SSBCI are referenced as additional eligibility requirements. We are also finalizing paragraph (e)(34)(iii) without the phrase ''items and services'' to avoid any implication that SSBCI that are reductions in cost sharing are not included in the SSBCI disclaimer requirement. The SSBCI disclaimer is required for all marketing and communications materials that mention SSBCI of any type. The new SSBCI disclaimer requirements, as finalized here, will apply to all contract year 2025 marketing and communications beginning October 1, 2024, and in subsequent years.

C. Agent Broker Compensation

Agents and brokers are an integral part of the MA and Part D industry, helping millions of Medicare beneficiaries to learn about and enroll in Medicare, MA plans, and PDPs by providing expert guidance on plan options in their local area, while assisting with everything from comparing costs and coverage to applying for financial assistance. Pursuant to section 1851(j)(2)(D) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet beneficiaries' health care needs. In September 2008, we published the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs interim final rule (73 FR 54237), our first regulation to establish requirements for agent and broker compensation, which included certain limitations on agent and broker compensation and other safeguards. In that rulemaking, we noted that these reforms addressed concerns that the previously permitted compensation structure resulted in financial incentives for agents to only market and enroll beneficiaries in some plan products and not others due to larger commissions. These incentives potentially resulted in beneficiaries being directed towards plans that were not best suited to their needs.

In that interim final rule, we noted that depending on the circumstances, agent and broker relationships can be problematic under the federal anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value, compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment targets. These and other fraud and abuse risks exist among the current agent and broker relationships. We note that the HHS Office of the Inspector General (OIG) advisory opinion process is available to parties seeking OIG's opinion as to the legality of a particular arrangement. Information about this process remains available on the OIG's website at *http://oig.hhs.gov/fraud/advisoryopinions.html.* CMS has also periodically made updates to the agent and broker compensation requirements in subsequent rulemaking (73 FR 67406).

It has become apparent that the growth of MA and changes in MA marketing warrant further updates to ensure the appropriate guardrails are in place to protect beneficiaries and support competition. For example, shifts in the industry and resulting changes in contract terms offered to agents and brokers and other third-party marketing organizations (TPMOs) for enrollment-related services and expenses warrant further action to ensure compliance with statutory requirements and that the compensation paid to agents and brokers incentivizes them to enroll individuals in the MA plan that is intended to best meet their health care needs. CMS has also observed that the MA marketplace, nationwide, has become increasingly consolidated among a few large national parent organizations, which presumably have greater capital to expend on sales, marketing, and other incentives and bonus payments to agents and brokers than smaller market MA plans. This provides a greater opportunity for these larger organizations, either directly or through third parties, to use financial incentives outside and potentially in violation of CMS's rules to encourage agents and brokers to enroll individuals in their plan over a competitor's plan. For example, CMS has seen web-based advertisements for agents and brokers to work with or sell particular plans where the agents and brokers are offered bonuses and perks (such as golf parties, trips, and extra cash) framed as allowable administrative add-ons in exchange for enrollments. These payments, while being presented to the agents and brokers as bonuses or incentives, are implemented in such a way that allows the plan sponsor, in most cases, to credibly account for these anti-competitive payments as ''administrative'' rather than ''compensation'' and these payments are therefore not limited by the existing regulatory limits on compensation. We note these payments may implicate and, depending on the facts and circumstances, potentially violate the Federal anti-kickback statute.

CMS has also received complaints from a host of different organizations, including state partners, beneficiary advocacy organizations, and MA plans, among others. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have

created an environment similar to what prompted CMS to engage in the original agent and broker compensation rulemaking in 2008, where the amounts being paid for activities that MAOs do not characterize as ''compensation,'' are rapidly increasing. The result is that agents and brokers are presented with a suite of questionable financial incentives that are likely to influence which MA plan an agent encourages a beneficiary to select during enrollment.

We believe these financial incentives are contributing to behaviors that are driving an increase in beneficiary marketing complaints received by CMS in recent years. As was discussed in our most recent Medicare Program Contract Year 2023 Rule, based on the most recent data available at that time, in 2021, CMS received more than twice the number of beneficiary complaints related to marketing of MA plans compared to 2020, and for some states those numbers were much higher (87 FR 27704 through 27902). These complaints are typically filed by enrollees or their caregivers with CMS through 1–800–Medicare or CMS regional offices, and generally allege that a beneficiary was encouraged or pressured to join an MA plan, and that once enrolled, the plan was not what the enrollee expected or what was explained to them when they spoke to an agent or broker.

In the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22234 through 22256), which appeared in the **Federal Register** on April 12, 2023, we discussed at length the rapidly increasing use of various marketing activities that typically result in beneficiaries being connected with agents and brokers to be enrolled in MA plans. Based on a number of complaints CMS reviewed, as well as audio recordings of sale calls, it appears that the increased marketing of 1–800 numbers to facilitate enrollment in MA plans through national television advertisements combined with the subsequent actions of agents and brokers when beneficiaries responded to those ads resulted in beneficiary confusion. In some instances, through listening to call recordings, CMS observed that when beneficiaries reached an agent or broker in response to these television ads, the beneficiary was often pressured by the agent or broker to continue with a plan enrollment even though the beneficiary was clearly confused.

At the same time, these types of complaints have escalated at a pace that mirrors the growth of administrative or add-on payments, which we contend are being misused to pay agents and brokers over and above the CMS-set compensation limits on payment to agents and brokers. CMS is concerned that when the value of administrative payments offered to agents and brokers reaches the levels that CMS has observed in recent years, these payments may distort the process that agents and brokers are expected to engage in when they assist beneficiaries in weighing the merits of different available plans. This distortion disadvantages beneficiaries who enroll in a plan based on the recommendation or encouragement of an agent or broker who may be influenced by how much or what kind of administrative payment the agent or broker expects to receive, rather than enrolling the beneficiary in an option that is intended to best meet the beneficiary's health care needs.

Consequently, the rise in MA marketing complaints noted previously suggests that agents and brokers are being influenced to engage in high pressure tactics, which may in turn cause beneficiary confusion about their enrollment choices, to meet enrollment targets or earn ''administrative payments,'' either directly or on behalf of their employer or affiliated marketing organization, in excess of the capped compensation payment set by CMS. Although CMS' existing regulations already prohibit plans, and by extension their agents and brokers, from engaging in misleading or confusing communications with current or potential enrollees, in the proposed rule we noted that additional limitations on payments to agents and brokers may be necessary to adequately address the rise in MA marketing complaints described here.

Additionally, while our proposed rule largely focused on payments and compensation made to agents and brokers, we noted that CMS is also concerned about how payments from MA plans to TPMOs may further influence or obscure the activities of agent and brokers. In particular, CMS expressed interest in the effect of payments made from MA plans to Field Marketing Organizations (FMOs), which is a type of TPMO that employs or is affiliated with agents and brokers to complete MA enrollment activities, which have increased in influence in recent years. FMOs may also conduct additional marketing activities on behalf of MA plans, such as lead generating and advertising. In fact, at the time of our first agent and broker compensation regulation, CMS expressed concern about amounts paid to FMOs for services that do not necessarily relate directly to enrollments completed by the agent or broker who deals directly with the beneficiary (73 FR 54239). Some examples of such services are training, material development, customer service, direct mail, and agent recruitment.

As we noted in the preamble to the two interim final rules published in 2008 (73 FR 67406 and 73 FR 54226), all parties should be mindful that their compensation arrangements, including arrangements with FMOs and other similar type entities, must comply with the fraud and abuse laws, including the federal anti-kickback statute. Beginning as early as 2010, an OIG report indicated that ''plan sponsors may have created financial incentives that could lead FMOs to encourage sales agents to enroll Medicare beneficiaries in plans that do not meet their health care needs. Because FMOs, like sales agents, may influence Medicare beneficiaries' enrollment in MA plans, CMS should issue additional regulations more clearly defining how and how much FMOs should be paid for their services.'' [153] In the time since CMS first began to regulate agent and broker compensation, we have seen the FMO landscape change from mostly smaller, regionally based companies to a largely consolidated group of large national private equity-backed or publicly-traded companies.

Finally, in addition to the undue influence that perks, add-on payments, volume bonuses and other financial incentives that are paid by MA organizations to FMOs may have on agents and brokers, they also create a situation where there is an unlevel playing field among plans. Larger, national MA plans are likely able to more easily shoulder the added costs paid to FMOs, as compared to smaller, more locally based MA plans. Furthermore, we have received reports that some larger FMOs are more likely to contract with large national plans rather than smaller regional plans, negatively impacting competition. On July 9, 2021, President Biden issued Executive Order (E.O.) 14036: ''Promoting Competition in the American Economy,'' (hereinafter referred to as E.O. 14036). E.O. 14036 describes the Administration's policy goals to promote a fair, open, competitive marketplace, and directs

[153] Levinson, Daniel R, BENEFICIARIES REMAIN VULNERABLE TO SALES AGENTS' MARKETING OF MEDICARE ADVANTAGE PLANS (March 2010); *https://oig.hhs.gov/oei/reports/oei-05-09-00070.pdf.*

the U.S. Department of Health and Human Services to consider policies that ensure Americans can choose health insurance plans that meet their needs and compare plan offerings, furthering competition and consumer choice. The regulatory changes included in the 2023 proposed rule also aimed to deter anti-competitive practices engaged in by MA organizations, agents, brokers, and TPMOs that prevent beneficiaries from exercising fully informed choice and limit competition in the Medicare plan marketplace among Traditional Medicare, MA plans, and Medigap plans.

CMS is concerned that the more recent increases in fees being paid to larger FMOs have resulted in a ''bidding war'' among MA plans to secure anti-competitive contract terms with FMOs and their affiliated agents and brokers. If left unaddressed, such bidding wars will continue to escalate with anti-competitive results, as smaller local or regional plans that are unable to pay exorbitant fees to FMOs risk losing enrollees to larger, national plans who can. In addition to seeking comment to help us develop additional regulatory action, we specifically requested comments regarding how CMS can further ensure that payments made by MA plans to FMOs do not undercut the intended outcome of the agent and broker compensation proposals included in this final rule; we thank commenters for the wealth of information they have shared and we will continue to integrate this new knowledge as we explore potential future rulemaking.

In addition, the comments that we received in response to the November 2023 proposed rule indicate that there is, in fact, an additional force at work in misaligning the incentives of agents and brokers enrolling Medicare beneficiaries into MA plans. Commenters brought to our attention that agents and brokers who are direct employees of FMOs, call centers, and other TPMOs typically receive an annual salary from their employer. We note that the salary received by employees of a TPMO from their employer does not currently fall under our regulatory definition of ''compensation.'' Commenters stated that an agent who is not directly employed by a call center may receive renewal payments for a beneficiary who remains enrolled in the plan that agent has helped the beneficiary select. By contrast, commenters also stated that a call center employee who is salaried may never be eligible to receive renewal payments and may only be incentivized to generate new enrollments. In this way, commenters expressed concerns that the incentives between the two types of agents and brokers may be different, and so a one-size fits all approach to regulating agent and broker compensation for all agents who enroll beneficiaries into MA plans has inherent limitations. This is an area of policy we will consider in future rulemaking.

As noted previously, sections 1851(j)(2)(D) and 1851(h)(4)(D) of the Act direct the Secretary to set limits on compensation rates to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs,'' and that the Secretary ''shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.'' In this final rule, we are focusing on current payment structures, including the use of administrative payments, among MA organizations and agents, brokers, and TMPOs, specifically FMOs, that may incentivize some agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary's needs, leading to enrollment in a plan that does not best fit the beneficiary's needs and a distortion of the competitive process.

Our regulations at § 422.2274 set out limitations regarding various types of payments and compensation that may be paid to agents, brokers, and third parties who represent MA organizations. Each of these limitations is intended to better align the professional incentives of the agents and brokers with the interests of the Medicare beneficiaries they serve. Our regulations specify maximum compensation amounts that may be paid to agents and brokers for initial enrollment and renewals. The regulations also currently allow for payment to agents and brokers for administrative costs such as training and operational overhead, as long as the payments are at or below the value of those services in the marketplace. The maximum compensation for initial and renewal enrollments and the requirement that administrative payments reflect fair market value for actual administrative services have been intended to ensure incentives for agents and brokers to help enroll beneficiaries into MA plans that best meet their health care needs.

However, while CMS has affirmatively stated the types of allowable payment arrangements and the parameters for those payments in regulations at § 422.2274, as previously discussed, some recent studies suggest that MA plans offer additional or alternative incentives to agents and brokers, often through third parties such as FMOs, to prioritize enrollment into some plans over others. These incentives are both explicit (in the form of higher payments purportedly for administrative services) and implicit (such as in the case of passing on leads, as discussed later in this section).[154]

As previously mentioned, we believe payments categorized by MA organizations as ''administrative expenses,'' paid by MA organizations to agents and brokers, have significantly outpaced the market rates for similar services provided in non-MA markets, such as Traditional Medicare with Medigap. This is based on information shared by insurance associations and focus groups and published in research articles by groups such as the Commonwealth Fund, which found that ''most brokers and agents in the focus groups recalled receiving higher commissions [total payments, including compensation and administrative payments]—sometimes much higher—for enrolling people in Medicare Advantage plans compared to Medigap.'' [155]

Similarly, some MA organizations are paying for things such as travel or operational overhead on a ''per enrollment'' basis, resulting in instances where an agent or broker may be paid multiple times for the same one-time expense, if the agent incurring the expense happened to enroll more than one beneficiary into the plan making the payment. For example, an agent could be reimbursed for the cost of traveling to an event where that agent enrolls a beneficiary into an MA plan; if the cost of travel is paid on a ''per enrollment'' basis, the agent would be reimbursed the price of the trip multiplied by the number of enrollments the agent facilitated while at that event. In this scenario, whichever MA organization reimburses for travel at the highest rates would effectively be offering a higher commission per enrollee, as the increased amount paid for travel, in additional to the allowable compensation, would be higher. While

[154] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (Feb. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents.*

[155] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (February. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents.*

this would not violate existing MA regulations, this would inherently create a conflict of interest for the agent. As statute requires that the Secretary ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs,'' we believe this type of conflict must be addressed.

We are also concerned that other activities undertaken by a TPMO, as a part of their business relationships with MA organizations, may influence the plan choices offered or how plan choices are presented by the agent or broker to a prospective enrollee. For example, we have learned of arrangements where a TPMO, such as an FMO, provides an MA organization with both marketing and brokering services. As part of the arrangement, the MA organization pays the FMO for leads generated by the FMO and then the leads are given directly to the FMO's agents instead of to the MA organization itself (or the MA organization's other contracted agents and brokers). When the FMO's agents then contact the individual and enroll the individual into an MA plan, the MA organization pays the agent or the FMO the enrollment compensation described in § 422.2274(d), separate and apart from any referral fee paid to the FMO under § 422.2274(f).

While MA organizations that are engaged in these types of arrangements (such as paying FMOs for lead generating activities and marketing, then giving the leads to the FMO's agents and then paying compensation for that same enrollment) might argue that they are not intending to influence an agent or broker in determining which plan ''best meets the health care needs of a beneficiary,'' we believe it is likely that these arrangements are having this effect. We believe that current contracts in place between FMOs and MA organizations can trickle down to influence agents and brokers in enrolling more beneficiaries into those plans that also provide the agents and brokers with leads, regardless of the appropriateness of the plan is for the individual enrollees. In fact, FMOs could leverage these leads as a form of additional compensation by ''rewarding'' agents who enroll beneficiaries into a specific plan with additional leads. Therefore, CMS is required under section 1851(j)(2)(D) of the Act to establish guidelines that will bring the incentives for agents and brokers to enroll individuals in an MA plan that is intended to best meet their health care needs, in accordance with the statute and as such is CMS' intention here.

In the proposed rule we proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation;'' and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We also proposed to make conforming edits to the agent broker compensation rules at § 423.2274. We will continue to monitor the MA marketing ecosystem and the influence of FMOs, lead generators, call centers, web-based sources, TV ads, and other fast-moving aspects of MA marketing to ensure beneficiaries are protected from misleading or predatory behavior while also having access to the information and support they need to make an informed decision about their Medicare coverage. For example, CMS will continue to monitor the behaviors addressed in this final rule at VI.A, which limit the distribution of personal beneficiary data by TPMOs (§§ 422.2274(g)(4) and 423.2274(g)(4)).

1. Limitation on Contract Terms

We proposed to add at § 422.2274(c)(13) that, beginning in contract year 2025, MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO, including FMO, has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary.

Examples of the anti-competitive contract terms we proposed to prohibit included, for instance, those that specify renewal or other terms of a plan's contract with an agent broker or FMO contingent upon preferentially higher rates of enrollment; that make an MA organization's contract with an FMO or reimbursement rates for marketing activities contingent upon agents and brokers employed by the FMO meeting specified enrollment quotas; terms that provide for bonuses or additional payments from an MA organizations to an FMO with the explicit or implicit understanding that the money be passed on to agents or brokers based on enrollment volume in plans sponsored by that MA organization; for an FMO to provide an agent or broker leads or other incentives based on previously enrolling beneficiaries into specific plans for a reason other than what best meets their health care needs.

As we explained in the November 2023 proposed rule, CMS believes that the proposed limitations on contract terms would give plans further direction as to the types of incentives and outcomes that must be avoided without being overly prescriptive as to how the plans should structure these arrangements.

We received the following comments on this proposal.

Comment: Commenters generally indicated their support for this proposal to require that MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best meets the health care needs of the beneficiary.

Response: We thank commenters for their support.

Comment: Some commenters requested additional information about the types of incentives and contract terms we intended to limit and the means by which we intend to enforce these restrictions.

Response: We thank commenters for their thoughtful input. While we recognize that it is impossible to anticipate every scenario that could present itself, it is important that we are clear in our meaning of the phrase ''direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best suits the beneficiaries' health care needs.''

Relying on a ''reasonableness standard,'' we would not, for example, read our regulation to prohibit MA plans from contracting with independent agents who have not been appointed to represent all possible competitors in a market. In this case, an agent who does not represent all possible competitors is inherently more likely to enroll beneficiaries into the plan(s) with which he or she is contracted. However, provided there is no contractual or financial incentive that would prevent the agent from choosing to seek additional arrangements and sell competitors' plans, the agent and the MAO(s) with which it contracts would be in compliance with our rule.

If, by way of another example, a TPMO or agent was offered a bonus or other payment by a plan or a TPMO

contracted by a plan or plans, in exchange for declining to represent a competing MA plan, this would be an example of a contract term that would likely violate the rule, as it is inherently anti-competitive in nature and on its face has the effect of encouraging enrollment in one plan over another based largely on the receipt of a financial reward for not representing or promoting a competitor plan's product.

Similarly, depending on the facts and circumstances, bonuses for hitting volume-based targets for sales of a plan may not be directly anti-competitive if they do not outwardly discourage or preclude a TPMO from marketing other plans, but it would likely have the indirect effect of creating an incentive for the TPMO to prioritize sales of one plan over another based on those financial incentives and not the best interests of the enrollees. Because the indirect effect of volume-based bonuses of this kind would be anti-competitive in nature, they would likely run afoul of the provision, and, like other potential scenarios described herein, could implicate fraud and abuse laws as well.

CMS expects to review contracts as part of routine monitoring, as well as relying on complaints and other methods of investigation, and work conducted by the Office of the Inspector General, to enforce this regulation. We also may pursue additional data collection regarding these contract arrangements as part of our established Part C reporting requirements process in future years.

After considering public comments, and the overwhelming support for this proposal, and for the reasons described in the November 2023 proposed rule and in our earlier responses, we are finalizing the policy as proposed at § 422.2274(c)(13) requiring that MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary; we are including one modification to the regulatory text to make clear that this requirement is applicable beginning with marketing and communications activities related to the 2025 contract year. We are continuing to consider whether additional guidance in this space may be necessary in future rulemaking.

2. Compensation Rates

Under current regulations, compensation for agents and brokers (described at § 422.2274(d)(2) and excluding administrative payments as described in § 422.2274(e)) may be paid at a rate determined by the MA organization but may not exceed caps that CMS calculates each year, based on fair market value (FMV) as specified at § 422.2274(a). For example, the CY2024 national agent/broker FMV compensation caps are $611 for each MA initial enrollment, $306 for a MA renewal enrollment, $100 for each Part D initial enrollment, and $50 for a Part D renewal enrollment.

We have learned that overall payments to agents and brokers can vary significantly depending on which plan an individual enrolls in. In the November 2023 proposed rule, we expressed concern that the lack of a uniform compensation standard across plans can encourage the types of arrangements that provide strong financial incentives for agents and brokers to favor some plans over others and that these incentives could result in beneficiaries enrolling in plans that do not best fit their needs. To eliminate this potential for bias and make certain that CMS' regulations governing agent and broker compensation ensure that agents and brokers are incented to enroll individuals in the MA plan that is intended to best meet their health care needs, we proposed to amend our regulations to require that all payments to agents or brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a), including payments for activities previously excluded under the definition of compensation at § 422.2274(a)(ii), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). We also proposed to make conforming amendments to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation; this proposal is further discussed in section VI.B. (X)(c) of this final rule, ''Administrative Payments.''

Further, we proposed to change the caps on compensation payments that are currently provided in § 422.2274 to set fixed rates that would be paid by all plans across the board. As proposed, agents and brokers would be paid the same amount either from the MA plan directly or by an FMO. We noted that our proposal does not extend to payments for referrals as described at § 422.2274(f); we believe the cap set on referral payments is sufficient to avoid the harms described previously, and that a referral payment is often made in lieu of a compensation payment, and so it does not provide the same incentives as compensation payments.

We believe that this approach may help level the playing field for all plans represented by an agent or broker and promotes competition. In addition, by explicitly saying that compensation extends to additional activities as a part of the relationship between the agent and the beneficiary, we reinforce CMS' longstanding understanding that the initial and renewal compensation amounts are based on the fact that additional work may be done by an agent or broker throughout the plan year, including fielding follow-up questions from the beneficiary or collecting additional information from a beneficiary.

Comment: A few commenters requested clarification regarding the timing and applicability of this proposed policy for the 2025 contract year and expressed concern that activities necessary to prepare for the 2025 contract year AEP begin far in advance of the 2025 calendar year. Commenters stated that a rule finalized in the Spring of 2024 with an effective date 60 days later may put many agents and brokers who have already begun securing their annual training, testing, and state appointments out of compliance before the AEP has even begun.

Response: We understand that the narrow timeline between finalization of this rule and the time at which agents and brokers will begin engaging in necessary and mandatory activities to prepare for the 2025 contract year may make it difficult for them to remain in compliance with this rule. In recognition of the timing concerns noted by commenters, we are the clarifying that applicability of these changes to §§ 422.2274 and § 423.2274 until October 1, 2024, so these updates will coincide with the beginning of marketing activities for the 2025 contract year. We are clarifying in our regulatory text that prior to that date, CMS's existing agent and broker compensation requirements will continue to apply, meaning that, for instance, arrangements between MAOs and TPMOs or agents that are not in compliance with our proposals will not be subject to remedial action for activities engaged in before October 1, 2024, even if they were related to 2025 contract year plans.

After considering feedback in public comments, we are finalizing our policy to require that, beginning with contract year 2025, all payments to agents or

brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a), including payments for activities previously excluded under the definition of compensation at § 422.2274(a)(ii), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). To memorialize this updated policy, we are finalizing an updated definition of compensation at § 422.2274(a) that will apply beginning with contract year 2025, meaning that MAOs and the TPMOs that they work with will need to begin to comply with these updated standards beginning on October 1, 2024, when marketing activities for contract year 2025 begin. We are also adopting language to the existing definition of compensation to make clear that this definition will apply for contract years through contract 2024, meaning that MAOs and TPMOs should continue to comply with CMS's existing agent and broker compensation policies until marketing activities for contract year 2025 begin on October 1, 2024. We are also finalizing our policy to make conforming amendments to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation, with an applicability date of October 1, 2024.

MA organizations are also currently required, under § 422.2274(c)(5), to report to CMS on an annual basis the specific rates and range of rates they will be paying independent agents and brokers. We proposed to remove the reporting requirement at § 422.2274(c)(5), as all agents and brokers would be paid the same compensation rate in a given year under our proposal.

We did not receive any comments on this aspect of our proposal and are finalizing it as proposed.

3. Administrative Payments

As discussed previously, CMS proposed that all payments to an agent or broker relating to the initial enrollment, renewal, or services related to a plan product would be included in the definition of compensation. For consistency with that proposed policy, we also proposed to incorporate ''administrative payments'' currently described at § 422.2274(e)(1) into compensation, and to amend § 422.2274(e)(2) to clarify that administrative payments would be included in the calculation of enrollment-based compensation beginning in Contract Year 2025. As we discussed in the proposed rule, we believe this step is necessary to ensure that MA organizations cannot utilize the existing regulatory framework allowing for separate payment for administrative services to effectively circumvent the FMV caps on agent and broker compensation. For instance, we stated in the November 2023 proposed rule that we understand that many plans are paying agents and brokers for conducting health risk assessments (HRAs) and categorize these HRAs as an ''administrative service.'' We understand the fair market value of these services, when provided by non-medical staff, to be approximately $12.50 per hour and the time required to complete an HRA is intended to be no more than twenty minutes.[156] However, we explained that we have been made aware of instances of an agent or broker enrolling a beneficiary into a plan, asking the enrollee to complete one of these short assessments, and then being compensated at rates of up to $125 per HRA. Compensation at these levels is not consistent with market value and CMS believes that compensation at these levels far exceeds the fair market value of the actual service being performed and therefore should not be categorized as an ''administrative service.'' Moreover, a study funded by the CDC to provide guidance for best practices ''recommend that HRAs be tied closely with clinician practice and be collected electronically and incorporated into electronic/patient health records [. . .] agents/brokers lack the necessary health care knowledge, information technology capabilities, and provider relationships to link HRAs in the recommended way.'' [157] For this reason, we believe that the HRAs completed by agents and brokers do not have the same value as those performed and interpreted by health care providers or in a health care setting.

Similarly, we explained in the November 2023 proposed rule that according to recent market surveys and information gleaned from oversight activities, payments purportedly for training and testing and other administrative tasks for agents and brokers selling some MA plans seem to significantly outpace payments for similar activities made by other MA plans, as well as payments for similar activities undertaken by insurance agents and brokers in other industries. The higher overall cost as compared to other industries, combined with the otherwise inexplicable difference in payments for administrative activities for some MA organizations compared to others, further points to the payment for these administrative activities being used as a mechanism to effectively pay agents and brokers enrollment compensation amounts in excess of the limits specified at § 422.2274(a) and (d).

By eliminating separate payment for administrative services, we stated that we expected that this proposal would eliminate a significant method which some plans may have used to circumvent the regulatory limits on enrollment compensation. Furthermore, we explained that we believed ensuring a fixed payment rate for agents will result in compensation greater than what is currently provided through typical contractual arrangements with FMOs, as there would no longer be a range of compensation rates at which the MA organizations could pay for agents and brokers' services. While our proposal would prohibit separate administrative payments, as described below, we proposed to adjust the FMV for compensation to take into account costs for certain appropriate administrative activities.

We recognized in the proposed rule that this approach could result in some agents and brokers being unable to directly recoup administrative costs such as overhead or lead purchasing from its compensation from Medicare health and drug plans, unless the agent has a certain volume of business. For instance, the cost of a customer relationship management (CRM) system (the software used to connect and log calls to potential enrollees) is estimated to be about $50 per month. Under our proposed rule, this expense would require at least one enrollment compensation per year to cover these costs, whereas under our current regulations it is currently permissible for an MA organization to pay for these costs directly, as administrative costs, leaving the entire compensation for enrollments as income for the agent or broker. However, we explained in the proposed rule that given the high volume of enrollees that use an agent or broker for enrollment services, we did

[156] CDC, Interim Guidance for Health Risk Assessments and their Modes of Provision for Medicare Beneficiaries; *https://www.cms.gov/files/document/healthriskassessmentscdcfinalpdf.*

[157] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (Feb. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents; cf.* Guidance on Development of Health Risk Assessment as Part of the Annual Wellness Visit for Medicare Beneficiaries—(Section 4103 of the Patient Protection and Affordable Care Act) *https://www.cdc.gov/policy/paeo/hra/hraawvguidancereportfinal.pdf.*

not believe there to be a large risk of agents or brokers failing to cross that initial threshold to recoup their administrative costs.

We also explained in the proposed rule that we considered an alternate policy proposal wherein we would maintain our current definitions of compensation and administrative payments but would remove the option for a plan to make administrative payments based on enrollment, as currently codified at § 422.2274(e)(2). We considered instead requiring that administrative payments be made a maximum of one time per administrative cost, per agent or broker. We considered the argument that these expenses, such as payments for training and testing, or nonmonetary compensation such as leads, should be paid at their FMV and not as a factor of overall enrollment because the value of such administrative tasks is usually a fixed rate, regardless of how many enrollments are ultimately generated by the agent or broker engaged in these administrative tasks.

We also considered whether, under this alternative policy approach, it would be best to require that each administrative expense be reimbursed at the same rate by each contracting MA organization as a means of encouraging agents and brokers to represent multiple plans at any given time. However, as we noted in the proposed rule, this alternative policy would, of necessity, be comparatively prescriptive and could present challenges for all parties as it relates to the tracking these expenses. We believe our proposal to include all payments to an agent or broker under the definition of compensation is likely to reduce the ability of plans and/or TPMOs to circumvent the maximum compensation rates defined by CMS via the annual FMV determination.

We sought comment on this proposal.

Comment: Similar to what we note previously, a few commenters requested clarification regarding the timing and applicability of this proposed policy for the 2025 Contract Year, and expressed concern that activities necessary to prepare for the 2025 contract year AEP begin far in advance of the 2025 calendar year, noting that if the rule was finalized in the Spring of 2024 and effective 60 days later, many agents and brokers would have already begun securing their annual training, testing, and state appointments out of compliance before the 2025 AEP has even begun.

Response: As previously stated, we understand that the narrow timeline between finalization of this rule and the time at which agents and brokers will begin engaging in necessary and mandatory activities to prepare for the 2025 contract year may make it challenging for them to remain in compliance, however, we believe that implementing these payment guardrails as soon as possible is necessary to protect the interests and health of Medicare beneficiaries. In recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a).

Comment: Many commenters expressed support for these proposals, indicating that they believe this move to make compensation amounts uniform for the sale of all plans will help curb the aggressive marketing tactics used by certain agents and brokers, and will reduce pressure placed on Medicare beneficiaries to enroll in plans that they do not fully understand, or which may not best suit their individual health care needs.

Response: We thank commenters for their support.

Comment: Many commenters stated that they supported this proposal because they believe it is important to make payments to agents and brokers clear and knowable, rather than subject to add-on administrative payments that are paid ''under the table'' and where neither CMS nor the consumer have any insight into these payment relationships or amounts.

Response: We thank commenters for their support and believe that by making compensation amounts universal, agents and brokers will hopefully be free from undue influence to enroll beneficiaries in one plan over another, but the beneficiaries themselves can be confident that their agent or broker is indeed working to ensure that they are enrolled in the MA plan that is best suited to meet their health care needs.

Comment: Some commenters expressed support for the proposal because it would enable small carriers to remain competitive with larger carriers, as they would not have to compete with larger carriers in offering ever-increasing incentives for agents, brokers, and TPMOs to represent these plans. Additionally, without additional incentives to increase steerage, smaller plans may have a better opportunity to compete in the marketplace.

Response: We thank commenters for their support of the proposal.

Comment: A commenter requested clarification about whether or how a plan could stop compensation for new enrollments in a plan mid-year if plans are no longer permitted to submit a range of compensation rates that would be applicable for that plan year.

Response: As proposed § 422.2274(d)(2) stated that for an initial enrollment year a plan may pay an agent or broker compensation at FMV. However, in proposing to set a fixed rate for compensation levels that plans ''may'' pay to agents and brokers, we did not intend to eliminate the option for a plan to choose not to pay compensation for an enrollment at all. Therefore, we are clarifying that under the regulations governing agent broker compensation at §§ 422.2274 and 423.2274 that CMS is adopting in this final rule, a plan may choose at any time to communicate to the agents and brokers representing it that it will no longer be compensating them for enrollments into that plan without being out of compliance of these regulations.

Comment: A few commenters expressed concerns that requiring plans to pay agents and brokers the same amount for compensation would have a negative impact on smaller MA organizations and Part D sponsors who may not be able to afford to pay the new uniform compensation rate and would therefore be unable to afford to pay agents and brokers to represent their plans.

Response: We understand the concern that smaller MA organizations may not be as well equipped to pay the mandatory compensation rate as a larger MA organization and will be prevented from negotiating with agents and brokers for a lower rate below the compensation cap as they can under our current rules. However, our data [158] suggests that negotiating below the payment cap was a very rare phenomenon, and we believe that the advantages gained by eliminating the continual increase in administrative payments, and therefore the need to increase payments made and offered to agents, brokers, and TPMOs will offset any financial losses caused by this increase to compensation expenses, as it is our understanding that the administrative fees paid per enrollee far exceed the compensation paid for that enrollment.

Comment: Many commenters disagreed with this proposal as a whole and argued that the types of aggressive marketing tactics we discussed in the preamble are most often engaged in by agents and brokers who are employees of FMOs and call centers, and that the incentives for these employed agents and brokers would not be mitigated by

[158] *https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/medicare-marketing-guidelines/agent-broker-compensation.*

our proposed compensation policies because employed agents receive a salary, whereas other independent agents and brokers make their living on commissions for enrollments. They contend that this policy, as a whole, does not distinguish between the different types of agents and their employment relationships, and is not narrowly targeted to rein in the abusive behaviors discussed.

Response: We thank commenters for their thoughtful comments and the information that they provided about the different types of relationships between agents and other TPMOs in the MA industry. We understand that, while our policy would have the desired effect of changing the incentives for some agents and brokers to ensure that they are aligned with the best interests of the Medicare beneficiaries whom they serve, there is a subset of agents and brokers who are directly employed by TPMOs—specifically FMOs and call centers—and these agents and brokers may not experience the same change in incentives because their salaried income may not be directly based on the CMS-defined compensation rates. We recognize that this distinction is an important part of the agent and broker ecosystem, and one which we will continue to explore as we contemplate future rulemaking.

However, we do not believe that the possibility that our policy may not reach a subset of the agents and brokers in this ecosystem is a reason not to finalize it. We believe this policy will have the desired effect of better aligning incentives for agents and brokers to ensure that they are enrolling beneficiaries in the MA plan that best meets the beneficiaries' health care needs, and not the plans that offer the agents and brokers the highest payments per enrollee. We also note that the policy to generally prohibit certain types of contract terms being finalized in this final rule at § 422.2274(c)(13), will afford a level of protection with regard to contract terms between MA organizations and TPMOs that direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker, including salaried agents and brokers, from being able to objectively assess and recommend which plan best fits the health care needs of a beneficiary. Importantly, MA organizations, agents, brokers, and other TPMOs also must comply with all applicable fraud and abuse laws including, but not limited to, the Federal anti-kickback statute.

Comment: Many commenters expressed their opposition to our proposal because many agents and brokers rely on the payment of administrative fees (sometimes also referred to as overrides) from an MA organization to their FMO to provide them with ''free'' services, such as access to plan comparison and enrollment tools, trainings, as well as contracting and compliance support. The FMOs are able to provide these ''free'' services to agents and brokers by negotiating with the MA organizations to pay the FMO the administrative fees associated with the agent or brokers' enrollments. Without the availability of such fees, commenters expressed concern that FMOs would no longer provide agents and brokers with these extra services without which they did not believe agents and brokers could effectively accomplish their enrollment work.

Response: We understand that removing the category of ''administrative payments'' (*i.e.* overrides), would change the current flow of payments from an MA organization to agents and brokers for an enrollment. We believe that by making the full payments directly to the agents and brokers, agents and brokers themselves will have the opportunity to decide which services are truly essential and how much those services are worth.

After considering public comments, we are generally finalizing our substantive proposal to include all payments to an agent or broker under the definition of compensation as proposed; in recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a). To memorialize this updated policy, we are finalizing our policy to incorporate ''administrative payments'' currently described at § 422.2274(e)(1) into compensation, and to amend § 422.2274(e)(2) to clarify that administrative payments would be included in the calculation of enrollment-based compensation beginning in Contract Year 2025. This means that that MAOs and the TPMOs that they contract or work with will need to begin to comply with these updated standards beginning on October 1, 2024, when marketing activities for contract year 2025 begin, per § 422.2263(a). We are also adopting language to the existing regulatory text to make clear that this definition will apply to contract years through contract year 2024, meaning that MAOs and TPMOs should continue to comply with CMS's existing agent and broker compensation policies until the date that marketing activities for contract year 2025 begin.

We also proposed to increase the compensation rate described at § 422.2274(a) to add certain appropriate administrative costs. In particular, we indicated that we believed that the administrative cost associated with the licensing, training and testing, and recording requirements at §§ 422.2274(b) and 422.2274(g)(2)(ii) may warrant an increase in the rate of compensation, given the significant and predictable cost of these mandatory activities.[159] Based on our fair market value analysis, we believed these activities would warrant increasing the base compensation rate by $31,[160] to be updated annually as part of the scheduled compensation rate update described at § 422.2274(a). Therefore, we proposed, beginning in 2025, that FMV would be increased by $31 to account for administrative payments included under the compensation rate, and to be updated annually in compliance with the requirements for FMV updates.

When proposed, we believed it was necessary to increase the rate for compensation by $31, based on the estimated costs for licensing, training, testing, and call recording that would need to be covered by this single enrollment-based payment. We proposed to begin with a one-time $31 increase, including various locality-specific adjustments, with annual FMV updates to this amount as described by the regulation, including ''adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries.'' In the November 2023 proposed rule, we also noted that we did not explicitly propose a proportionate increase to compensation for renewals and that we considered this in determining the amount by which we proposed to increase the rate for compensation for enrollments.

We sought comment on our proposal to increase the rate of compensation to account for necessary administrative costs that would be incorporated into this rate under our previous proposal. Specifically, CMS requested comment on the administrative costs that should be considered, and how else we might determine their value, as we consider the future of the compensation structure.

[159] *https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compenstation.*

[160] Our calculations arriving at this number are further discussed in the COI in section X.B.10 of this final rule, titled ICRs Regarding Agent Broker Compensation (§ 422.2274).

Comment: As in the previous policies, commenters indicated their concern that an effective date immediately after finalization of the policy would be difficult if not impossible to comply with.

Response: As with the modifications to the compensation rate discussed above, we are delaying the applicability date for the changes to the agent and broker compensation requirements at §§ 422.2274 (a), (c), and (d) to October 1, 2024, and therefore will not be applicable prior to the start of marketing and enrollment activity for the 2025 contract year.

In recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a).We believe that implementing these payment guardrails as soon as possible, will enhance the beneficiary experience with agents and brokers during the 2025 AEP. The benefit of this implementation date offsets any concerns about complexity or potential extra payment generated by this implementation framework.

Comment: A commenter requested clarification regarding how this proposal would affect renewals.

Response: As indicated in the proposed rule at 88 FR 78556, we did not separately propose a specific numeric increase in renewals proportionate to the proposed increase in initial compensation. However, the proposed regulation text governing renewal compensation, at § 422.2274(d)(3), as proposed, states that ''For each enrollment in a renewal year, MA plans may pay compensation at a rate of 50 percent of FMV.'' The reference to FMV within § 422.2274(d)(3) refers to the FMV for agent broker compensation specified in CMS's regulations at § 422.2274(a). Therefore, any updates to the FMV, including those which is CMS finalizing here, would automatically be incorporated into the calculation of compensation rate for renewals and would not need a separate proposal to achieve this result. See Tables FC–1 and FC–2 for more detail.

Comment: Many commenters indicated that CMS's proposed $31 increase to the flat-rate compensation amount would be insufficient to cover even the two primary activities we listed in the proposed rule (call recording and training and testing). Commenters indicated that agents and brokers have many other business expenses, such as plan comparison tools and appointment fees which were not included in calculating the rate update. Furthermore, some commenters explained that agents and brokers often engage in work and provide services that are unlikely to result in enrollment but are for the benefit of those beneficiaries, such as providing guidance to estate planners. We also heard from many commenters, including agents and brokers as well as beneficiaries, about additional services agents and brokers provide beneficiaries through their knowledge of plans and access to industry-standard technology; for instance, commenters noted that a local agent may help a beneficiary identify a plan that includes a preferred doctor, or help an enrolled beneficiary find the local in-network pharmacy with the lowest prices on that beneficiary's drugs.

Commenters argued that these activities, and the fair market value of the tools and services agents and brokers need to perform their jobs, warranted a significantly higher per-enrollee compensation rate. Some commenters suggested figures for a more appropriate compensation increase ranging from $50 to $500 more, per new enrollee, while others recommended that the increase be a percentage of the base compensation amount.

Commenters suggested that without sufficient compensation, many agents and brokers would no longer be able to serve the MA market, and new agents and brokers would not have the resources to enter the market in the first place.

Response: We thank the many commenters who provided us with a more complete picture of the many administrative and other services and expenses agents and brokers undertake when assisting beneficiaries with enrollments. These comments have made us aware that, in our initial proposal, we may not have adequately accounted for the array of services that agents and brokers may provide when we calculated our proposed payment increase. It was not our intention to make the MA compensation rate so low that agents and brokers would be driven out of the industry or would be unable to enter it in the first place.

However, we do believe it is important to ensure that, while we support agents and brokers and the services they provide, the MA program and its funds are not being used to subsidize other programs and industries. For example, we understand that in the proposed rule we may have undervalued the cost of CRM (customer-relationship management) tools which provide call recording software. However, it is our understanding that these tools serve additional functions beyond the mandatory call recording and transcription, and that this functionality may be used by an agent or broker when soliciting an enrollment for a non-Medicare, private market plan. Therefore, we believe that it is reasonable for MA compensation rates to reflect less than 100 percent of the cost of purchasing or licensing these tools.

After considering what we have learned and the many responses we received through public comment, we have concluded that our original proposed increase to compensation was too low. Commenters' feedback, both general and specific, was closely considered and we believe it is necessary to update the compensation rate increase to better reflect the costs of MA agent or broker services. Commenters suggested many different figures and means of calculating an appropriate amount. As discussed previously, the true cost of most administrative expenses can vary greatly from one agent or broker to another and is based in data and contracts that CMS does not have access to, so it would be extremely difficult for us to accurately capture, making a line-item calculation not practicable. This was further reflected in the wide variation among alternate rates posed by commenters, with a few commenters suggesting an alternate rate increase of $50, another $75, while the majority recommended higher rates beginning at $100 and some going as high as $500. Some commenters suggested that we should calculate the compensation increase as a percentage of the base rate, such as 30% or 33% of the current $611 compensation figure.

Considering the complexities involved, we believe that choosing a flat rate for calculating the increase is an appropriate path forward to create parity among agents, regardless of which plan, plan type, or type of Medicare enrollment they effectuate on behalf of the beneficiary. Administrative payments are intended to cover administrative costs faced by the agent or broker and those costs should be the same regardless of the type of plan in which a beneficiary enrolls, including a standalone PDP. Therefore, there is no need to vary administrative payments based on plan type and a flat rate approach is the most appropriate way to achieve our goal of eliminating financial incentives in the form of larger, purported administrative payments which are over and above FMV from a particular plan or plans, that may have the effect of encouraging agents and brokers to steer enrollment in one plan

or plan type versus another. A uniform, flat rate achieves this goal.

Several commenters suggested that an increase of $100 would be an appropriate starting point and reflects the minimum monthly costs of necessary licensing and technology costs. We understand that other commenters recommended an increase of more than $100, including some commenters that suggested an increase of $200 or more. However, we believe, based on the totality of comments that recommendations for an increase above $100 may have been inflated to include the full price of all technology and systems that are also utilized to effectuate sales in other markets or for different product types other than MA or PDP products. In addition, it appears that these higher dollar recommendations may reflect the agent and brokers' loss of ''bonus payments'' and other purported ''administrative payments'' they may previously have received, some of which were always beyond the scope and FMV of the services involved in enrolling beneficiaries into MA and PDP plans and therefore should not have been included under compensation or administrative payments.

We believe that increasing the FMV rate for new enrollments by a total of $100, and therefore applied to renewals at a maximum amount of 50 percent of the total compensation amount, should provide agents and brokers with sufficient funds to continue to access necessary administrative tools and trainings, to offset appointment fees and encourage the representation of multiple plans, and therefore to continue providing adequate service to Medicare beneficiaries. Accordingly, based on the information provided in comments and for the reasons discussed in this final rule, we are finalizing a policy to make a one-time $100 increase to the FMV compensation rate for agents and brokers for initial enrollments into MA plans for the 2025 plan contract year.

TABLE FC-1: AGENT BROKER COMPENSATION UPDATES CY 2024–2026

	2024	2025	2026
Initial Enrollment	$611	(FMV TBD) + $100	FMV TBD
Renewal	$305	(FMV TBD +100)*0.5	FMV TBD*0.5

By way of example, if we were to assume that the FMV increase in years 2025 and 2026 is 2.5 percent, the payment rates for those years would be as follows:

TABLE FC-2: EXAMPLE AGENT BROKER COMPENSATION UPDATES CY 2024-2026

	2024	2025	2026
Initial Enrollment	$611	$726	$744
Renewal	$305	$313	$372

Comment: Several comments expressed confusion about whether this payment is an ''all-in cap'' that is intended to include all fees paid by an MA organization to an agent, broker, or other TPMO, and what that would mean for payments related to marketing activities.

Response: This proposal, and all agent broker compensation rules at § 422.2274(d) are limited to independent agents and brokers, and do not extend to TMPOs more generally. Therefore, this policy represents a limitation on payments in excess of those paid under ''compensation'' only for commissions paid for enrollments to independent agents and brokers. Though we are continuing to consider future rulemaking in this space, our current policy does not extend to placing limitations on payments from an MAO to a TPMO who is not an independent agent or broker for activities that are not undertaken as part of an enrollment by an independent agent or broker.

After considering public comments on this proposal, for the 2025 contract year, we are finalizing at § 422.2274(a) a one-time FMV increase of $100, which will then be added to the base compensation rate for 2025; the sum of the 2025 compensation rate and the $100 will form a new base compensation rate that will be updated annually according to our FMV updates described in § 422.312. We are also finalizing changes to § 422.2274(d)(1)(ii) that beginning with contract year 2023, MA organizations are limited to the compensation amounts outlined in § 422.2274(a).

We received many out-of-scope comments related to agent and broker compensation as part of this rulemaking. We received many comments indicating the need for a regulatory distinction between agents employed by call centers and those who are truly independent and only contract with TPMOs. We appreciate these comments and will continue to explore ways in which further regulation in this space may further our goals of ensuring that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that best meets their health care needs.

We also received many comments encouraging more robust enforcement of our current regulations, and comments encouraging CMS to relax our rules somewhat to ensure that all agents have the ability to effectuate sales for all plans. We received feedback asking for more regulation in this policy space, and comments asking us to slow regulatory action to give the policies finalized in the past few years, time to mature. We have read and considered all comments and will consider these suggestions as we contemplate future rulemaking.

4. Agent Broker Compensation for Part D Plans

Finally, we also are finalizing our proposal to apply each of the policies described previously, governing agent and broker compensation for the sale of MA plans, to also apply to compensation for agents and brokers that market PDP plans, as codified at § 423.2274.

Pursuant to sections 1851(j)(2)(D) and 1860D–4(l) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the MA and Part D prescription drug plans that are intended to best meet beneficiaries' health care needs.

As we explained in the November 2023 proposed rule, because the same agents and brokers are often licensed to sell both MA plans and PDPs, we believe it is necessary under our statutory authority to apply the same compensation rules to the sale of both MA plans and PDPs in order to ensure that both plan types are being held to the same standards and are on a 'level playing field' when it comes to incentives faced by agents and brokers. This includes increasing the FMV rate compensation rate.

In the November 2023 proposed rule we also stated that we think it is necessary to extend these regulations to the sale of PDPs to avoid shifting the incentives discussed at length previously, such as the incentive for agents to favor one plan over another based upon bonuses or other payments that are not currently accounted for under the definition of ''compensation.'' If conforming changes are not made to the sale of PDP plans, the PDP plans may have an unfair advantage in that they have the opportunity to offer additional payments and perks to FMOs and agents, while MA plan sponsors are limited by the policies proposed previously. Therefore, for the same reasons that we described in the proposed rule for adopting the proposed changes to § 422.2274, we also proposed to make conforming amendments to § 423.2274.

We sought comment on this proposal, and specifically whether and to what extend modifications to these proposals should be made to account for differences between MA and Part D plan types.

We did not receive any comments on the proposal to extend these changes to the sale of PDP plans. Thus, we are finalizing updates to 42 CFR 423.2274 (a), (c), (d), and (e) largely as proposed. However, in light of the changes to the MA compensation rate described in section X.C.3. of this final rule and the need for parity between MA and PDP plan sales discussed in this section, we are conforming changes to the PDP compensation rates at § 423.2274 (to increase the PDP compensation rate for initial enrollments by $100. Likewise, where CMS is finalizing the regulation text in § 422.2274(a), (c), and (d) with minor organizational and editorial changes for clarity, we are adopting conforming changes to the regulation text that we are finalizing in § 423.2274(a), (c), and (d). Our policies are in alignment with the rules being finalized for MA agents and brokers, with an applicability date for these rules on October 1, 2024, for the 2025 plan contract year.

5. Summary of the Final Policy

We are finalizing the following policies with regard to agent and broker compensation:

- For contract year 2025 and subsequent contract years, generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may directly or indirectly interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs, as reflected in § 422.2274(c)(4) of this final rule.
- Set a single agent and broker compensation rate for all plans, as reflected in § 422.2274(d)(2), while revising the scope of what is considered ''compensation,'' applicable to contract year 2025 and subsequent contract years, as reflected in § 422.2274(a) and (e).
- Eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services, applicable to contract year 2025 and subsequent contract years, as reflected in § 422.2274(e).
- Make conforming edits to the PDP agent broker compensation rules at § 423.2274.

VII. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.164, 422.166, 422.260, 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 as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and based on 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 MA beneficiary rebates under section 1854(b) of the Act. 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 Parts 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526–27). As a result, the policies and regulatory changes finalized here will 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 apply to MA plans 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. To support the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality and value-based care programs. Across our programs, where applicable, we are considering including the Universal Foundation [161] of quality measures, which is a core set of measures that are aligned across CMS programs. CMS is committed to aligning a core set of measures across all our quality and value-based care programs and ensuring we measure quality across the entire care continuum in a way that promotes the best, safest, and most equitable care for all individuals. Improving alignment of measures across federal programs and with private payers would reduce provider burden while also improving the effectiveness

[161] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

and comparability of measures. Using the Universal Foundation of quality measures would focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The Universal Foundation is a building block to which programs would add additional aligned or program-specific measures. This core set of measures would evolve over time to meet the needs of individuals served across CMS programs. We submitted the Initiation and Engagement of Substance Use Disorder Treatment (IET) measure (Part C) (a Universal Foundation measure) to the 2023 Measures under Consideration list as part of the Pre-Rulemaking Measure Review process as a step toward proposing use of that measure in the Star Ratings system through future rulemaking to align with the Universal Foundation. We also note that, beginning with measurement year 2023, Part C contracts are beginning to report to CMS additional measures that are part of the Universal Foundation, such as Adult Immunization Status, Depression Screening and Follow-Up for Adolescents and Adults, and Social Need Screening and Intervention, for the display page. We have previously solicited feedback regarding potentially proposing these measures as Star Ratings in the future through both 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 the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. We intend to submit these measures to the Pre-Rulemaking Measure Review process in the future and propose them through future rulemaking as additional Star Ratings measures. The remaining measures that are part of the Universal Foundation are already part of the current Part C and Part D Star Ratings program.

In the December 2022 proposed rule, in addition to the policies addressed in the April 2023 final rule,[162] we proposed to make changes in the specific measures used in the Star Ratings System:

- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the National Committee for Quality Alliance (NCQA) specification change;
- Add the updated Part C Care for Older Adults—Functional Status Assessment measure with the NCQA specification change;
- 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 also proposed a series of technical clarifications of the existing rules related to Quality Bonus Payment (QBP) appeals processes and weighting of measures with a substantive specification change.

In the December 2022 proposed rule, we proposed these changes to apply to the 2024 measurement period and the 2026 Star Ratings, but as discussed in and given the timing of this final rule, we are finalizing these policies (that is, data would be collected, and performance measured) for the 2025 measurement period and the 2027 Star Ratings unless otherwise stated.

In the November 2023 proposed rule, we proposed to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D). We also proposed the following methodological enhancements, clarifications, and operational updates:

- Revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures.
- Update how the Categorical Adjustment Index (CAI) and health equity index (HEI) reward are calculated in the case of contract consolidations.
- Revise an aspect of the QBP appeals process.
- Add that a sponsor may request CMS review of its contract's administrative claims data used for the Part D Patient Safety measures no later than the annual deadline set by CMS for the applicable Star Ratings year.

Unless otherwise stated, finalized changes would apply (that is, data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings.

CMS appreciates the feedback we received on our proposals in both proposed rules. In the sections that follow, which are arranged by topic area, we summarize each proposal and comments we received and provide our responses.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Star Ratings program. 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 (83 FR 16532) hereinafter referred to as the April 2018 final rule, 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. 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.

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. For example, we regularly review measures developed by

[162] In the April 2023 final rule, we finalized several policies from the December 2022 proposed rule, including the introduction of a health equity index reward and removal of the existing reward factor starting with the 2027 Star Ratings and a series of measure updates: removing the Part C Diabetes Care—Kidney Disease Monitoring measure; updating the Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures; and adding the Part C Kidney Health Evaluation for Patients with Diabetes measure. In the April 2023 final rule, we also finalized several methodological changes: reducing the weight of patient experience/complaints and access measures; adding an additional basis for the subregulatory removal of Star Ratings measures; and removing the 60 percent rule for the adjustment for extreme and uncontrollable circumstances. Finally, we also finalized a series of technical clarifications of the existing rules related to adjustments for disasters and contract consolidations, as well as a technical amendment to §§ 422.162(a)(2)(i) and 423.186(a)(2)(i) to fix a codification issue. 88 FR 22263 through 22297.

NCQA and Pharmacy Quality Alliance (PQA).

1. Measure Removals

a. Medication Reconciliation Post-Discharge (Part C)

We proposed 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 included beginning with the 2024 Star Ratings. In the January 2021 final rule at 86 FR 5921–24, CMS finalized inclusion of the TRC measure (Part C) 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 Star Ratings as a stand-alone measure and as one of the four indicators included in the TRC measure. As discussed at 86 FR 5921–24, 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. 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 5921–22. 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 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 proposed to remove the stand-alone MRP measure from the Part C Star Ratings 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 for Part C Star Ratings. We solicited comments on this proposal.

Comment: Most commenters supported the removal of the MRP measure. Some commenters raised concerns regarding having both the stand-alone MRP measure and having MRP as a component of the TRC measure for a period of time until the stand-alone measure is retired. A few commenters suggested the removal of the MRP measure should coincide with the addition of the TRC measure, which was added to the 2024 Star Ratings.

Response: We thank the commenters for their support of our proposal. The stand-alone MRP measure is being removed beginning with the 2025 measurement year, which provides MA organizations with notice of the measures being used for quality ratings in advance of the measurement year. During this interim period, having MRP as a stand-alone measure as well as a component of the TRC measure gives it a slightly higher weight in the Star Ratings. Since both the stand-alone MRP measure and the TRC measure are weighted as process measures (which is a weight of 1), the weight of MRP across these two measures is still relatively low. In light of this and the importance of reconciling medications following an inpatient stay, we do not believe that the short period during which both the MRP measure and the TRC measure are included in the Part C Star Ratings is problematic.

Comment: A commenter noted that plans will be disincentivized to focus on MRP once the stand-alone measure is removed.

Response: We understand the commenter's concern but note that plans should continue focusing on reconciling medications following an inpatient stay given this also impacts the TRC measure and other measures in the Star Ratings such as reducing hospital readmissions and improving care coordination.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the removal of the MRP measure from the Part C Star Ratings starting with the 2025 measurement year and the 2027 Star Ratings.

2. 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 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 proposed 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 proposed expanding the age range for the Colorectal Cancer Screening measure to adults aged 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) that participate in Exchanges [163] and the adult core set for

[163] *https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf.*

Medicaid plans,[164] have introduced 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. We first displayed the updated measure for the 2022 measurement year, on the 2024 display page.

We solicited comments on this proposal.

Comment: Most commenters strongly supported CMS expanding the age range for the Colorectal Cancer Screening measure to include beneficiaries starting at age 45, with many citing data on the importance of earlier colorectal cancer screenings.

Response: We appreciate the support to expand the age range for the colorectal cancer screening measure, following updated clinical guidelines established by the USPSTF.

Comment: A commenter was concerned that the expanded age range may negatively impact the measure rate because more enrollees will be included in the denominator.

Response: We strive to ensure the Star Rating measures reflect the most recent clinical guidelines. The USPSTF recommends offering colorectal cancer screening at age 45 due to recent trends of increasing colorectal cancer in adults younger than 50 years old and the benefits of screening in reducing cancer diagnoses. CMS will maintain the legacy measure with the narrower age range in the Star Ratings through the end of the 2024 measurement year and the 2026 Star Ratings. Because the updated measure with the broader age range has been on the display page beginning with the 2022 measurement period, plans will have a total of 3 measurement years to transition to the most recent clinical guidelines, which are reflected in the updated measure. We do not believe that additional time is necessary or appropriate because the change in the USPSTF recommendation was nearly 3 years ago as of the time this final rule is published. Ensuring that the Star Ratings reflect up to date clinical guidelines is an important consideration both for providing comparative information to beneficiaries about MA plan quality and ensuring that the MA program furnishes appropriate care and access to covered services.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing expanding the age range for the Colorectal Cancer Screening measure. Given the timing of the finalization of this rule, we are finalizing the addition of the Colorectal Cancer Screening measure with the expanded age range starting with the 2025 measurement year and the 2027 Star Ratings. Table VII.1 summarizes the updated Colorectal Cancer Screening measure finalized in this rule. The measure description listed in this table is a high-level description.

b. Care for Older Adults—Functional Status Assessment (Part C)—Substantive Change

We proposed to add the Care for Older Adults (COA)—Functional Status 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 data reported in 2021, based on the 2020 measurement year, NCQA implemented a change for the COA—Functional Status Assessment.[165] 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), and (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 data reported in 2021.

The measure change for the COA—Functional Status Assessment measure is a substantive update 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 proposed 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 ADLs were assessed; (2) notation that IADLs were assessed; or (3) result of assessment using a standardized functional assessment tool.

We solicited comments on this proposal.

Comment: Most commenters supported returning the updated COA—Functional Status Assessment measure back to the Star Ratings noting the importance of assessing functional status in older beneficiaries.

Response: We thank the commenters for their support of our proposal.

Comment: A commenter raised concerns with duplicative efforts in monitoring functional status in the Star Ratings program since it includes other measures such as the SNP Care Management measure and the Physical Functioning Activities of Daily Living (PFADL) measure.

Response: We disagree that this measure duplicates information and performance monitored through other measures. The PFADL measure is currently on the display page and is different than the COA—Functional Status Assessment measure in that it measures changes in functional status over time for all MA enrollees, not only SNP enrollees, and does not measure whether an enrollee had an assessment. The SNP Care Management measure is broader in that it focuses on whether a SNP enrollee had an assessment of their health needs and risks and is not about assessments specifically of functional status.

Comment: A commenter recommended delaying the return of this measure to the Star Ratings until NCQA decides whether the measure will be retired because the 2024

[164] *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html.*

[165] We solicited feedback on these changes in the Advance Notice of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

Advance Notice noted that NCQA was considering an alternative measure that may replace the COA—Functional Status Assessment measure.

Response: At this time NCQA is no longer considering the retirement of this measure and there is therefore no reason to delay the return of this measure to the Star Ratings.

Comment: A commenter requested additional guidance as to how the HEDIS measure specifications delineate ''standardized functional assessment tools.''

Response: In Volume 2 of the HEDIS Technical Specifications for Health Plans,[166] there are examples of standardized functional status assessment tools that may be used to satisfy the measure, such as the SF–36,® Assessment of Living Skills and Resources (ALSAR), Independent Living Scale (ILS), Katz Index of Independence in ADL, Klein-Bell ADL Scale, Lawton & Brody's IADL scales, and Patient Reported Outcome Measurement Information System (PROMIS) Global or Physical Function Scales.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing adding back the COA—Functional Status Assessment measure to the Star Ratings. Given the timing of the finalization of this rule, we are finalizing the addition of the COA—Functional Status Assessment measure starting with the 2025 measurement year and the 2027 Star Ratings. Table VII.1 summarizes the updated COA—Functional Status Assessment measure finalized in this rule. The measure description listed in this table is a high-level description.

c. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D)—Substantive Change

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).

CMS also uses the MTM Program Completion Rate for CMR measure, which is defined as the percent of MTM program enrollees who received a CMR during the reporting period to show how many members in a plan's MTM program had an assessment from their plan by a pharmacist or other health professional to help them manage their medications. As part of the completion of a CMR, a Part D enrollee receives a written summary of the discussion in CMS's Standardized Format, including an action plan that recommends what the member can do to better understand and use their medications.[167]

In the December 2022 proposed rule, CMS proposed changes to the MTM program targeting criteria, including: (1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases [168] 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). We estimated that the proposed changes would increase the number and percentage of Part D enrollees eligible for MTM from 4.5 million (9 percent) to 11.4 million (23 percent).

As noted in the April 2023 final rule, we did not address comments received on the provisions of the proposed rule that were not finalized in that rule, such as the proposed MTM program targeting criteria changes, and stated that they would be addressed at a later time, in a subsequent rulemaking document, as appropriate. If those proposed changes were to be finalized, the number of Part D enrollees eligible for MTM programs would increase, and the denominator of the MTM Program Completion Rate for CMR measure would expand accordingly; therefore, such changes in the targeting criteria would be substantive updates to the Star Rating measure per § 423.184(d)(2). Specifically, the proposed changes to the targeting criteria would not update the actual measure specifications but would meaningfully impact the number of Part D enrollees eligible for MTM services from 9 percent to an estimated 23 percent and, thus, substantially increase the number of enrollees included in the denominator of the MTM Program Completion Rate for CMR measure, if finalized.

Accordingly, CMS proposed that if the changes to eligibility for the MTM program in the December 2022 proposed rule (as previously described) are finalized, we would move the MTM Program Completion Rate for CMR measure to the display page for at least 2 years due to substantive measure updates associated with the change in MTM program eligibility criteria (88 FR 78558). Since there is no change to the measure specifications other than the eligibility for the MTM program, there would be no legacy measure to calculate while the updated measure is on the display page. The MTM-eligible denominator population would have meaningfully increased due to changes in the program requirements, and CMS would not have the means to calculate the measure using the previous MTM eligibility criteria. Therefore, we proposed that the measure would be removed from the Star Ratings entirely for the 2025 and 2026 measurement years and would return to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. CMS did not anticipate any additional burden associated with the measure update, as burden tied to the changes in the MTM eligibility criteria was already considered in estimates for the December 2022 proposed rule. Under our proposal for the MTM Program Completion Rate for CMR measure, if the proposed changes to eligibility for MTM programs were not finalized, CMS would not make any substantive changes to the measure—that is, we would also not finalize the proposal in this rule to update the Star Rating measure. Readers should refer to section III.E. of this final rule for discussion of proposal to change the MTM program eligibility criteria.

We invited public comment on this proposal to update the MTM Program Completion Rate for CMR measure and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal to move the MTM Program Completion Rate for CMR measure to the display page for at

[166] *https://www.ncqa.org/hedis/measures/.*

[167] The Medicare Part C & D Star Ratings Technical Notes provide details on existing measures and are available at: *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.*

[168] 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 (*).

least two years if the proposed changes to the MTM program targeting criteria are finalized.

Response: We appreciate the supportive comments. As discussed in section III.E. Part D MTM Program in this final rule, CMS is finalizing changes to the targeting criteria at § 423.153(d)(2). CMS estimates that the number of Part D enrollees eligible for MTM will increase from 3.6 million (7 percent of Part D enrollees) to 7.1 million (13 percent of Part D enrollees) based on updated 2022 data.

Comment: A few commenters specifically did not support moving the MTM Program Completion Rate for CMR measure to the display page because they do not support changes to the MTM program targeting criteria. A few commenters expressed concern regarding the increased impact of the remaining Part D Star Rating measures if the MTM Program Completion Rate for CMR measure was moved to the display page and not included in the Star Ratings.

Response: Refer to section III.E. Part D MTM Program section in this final rule for information on the MTM program changes that will be applicable on January 1, 2025. Comments on the substance of the changes to the Part D MTM program that were timely received (that is, received during the comment period for the December 2022 proposed rule, which closed February 13, 2023) are addressed in that section.

We understand the concerns raised by commenters that there would be one less Part D measure included in the calculations to determine the overall Star Rating for MA–PD plans and/or the Part D summary Star Rating; however, there is no legacy measure to include in the Star Ratings because the MTM-eligible population for the denominator would change. Due to these substantive increases to the MTM-eligible measure denominator population, and the rules for substantive measure updates per § 423.184(d)(2), the MTM Program Completion Rate for CMR measure must move to the display page for at least 2 years before using the updated measure in the Star Ratings. While on the display page, CMS will continue to monitor the rates as the MTM program eligibility criteria changes are implemented.

Comment: A few commenters suggested that CMS work with a measure steward, such as the PQA, to develop alternate or companion measures that measure the success or impact of MTM services on health outcomes. A commenter recommended that CMS implement the PQA Medication Therapy Resolution Monitoring metric.

Response: CMS encourages the industry and the PQA to develop new MTM quality measures that CMS may consider for use in the Star Ratings program in the future. We believe the commenter was referencing the PQA's Medication Therapy Problem Resolution monitoring measure. According to the PQA, monitoring measures such as this do not fit the characteristics or intended use of a performance measure.[169]

After consideration of the comments received, we are finalizing the proposed update to move the MTM Program Completion Rate for CMR measure to the display page for at least two years before adding it to the Star Ratings. As discussed in section III.E. in this final rule, CMS is finalizing changes to the targeting criteria at § 423.153(d)(2) that will be effective on January 1, 2025. Therefore, the MTM Program Completion Rate for CMR measure will move to the display page entirely for the 2025 and 2026 measurement years and would return as a new measure to the Star Ratings program for the 2027 measurement year for the 2029 Star Ratings. Table VII.1 summarizes the updated MTM Program Completion Rate for CMR measure finalized in this rule.

3. Measure Additions

a. 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)

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 the PQA.

CMS proposed to add the following three Part D measures to the 2026 Star Ratings (2024 measurement year), which are measures developed by the PQA: COB, Poly-ACH, and Poly-CNS. The new Part D measures are calculated from Prescription Drug Event (PDE) or CMS administrative data, so they do not require any new data collections. Additionally, as announced in the Advance Notice of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies [170] the added measures would 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).

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 during the measurement period.
- 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 anticholinergic 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 measures help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and help plans encourage appropriate prescribing when medically necessary.

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 Star Ratings measures. In addition, these measures 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, and were reviewed by the Measure Applications Partnership (MAP) for input and recommendations to HHS on measure selection for CMS programs.[171] The Polypharmacy measures received conditional support for rulemaking pending additional consensus based entity (CBE) endorsement (that is, approval and full support for rulemaking was conditional only because the measure was not

[169] *https://www.pqaalliance.org/pqa-measures s.*

[170] Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies at *https://www.cms.gov/files/document/2024-advance-notice.pdf.*

[171] Pre-Rulemaking MUC Lists and Recommendation Reports at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

already National Quality Forum (NQF) endorsed), and the COB measure is a CBE-endorsed measure by NQF; therefore, the COB measure received support for rulemaking. NQF endorsement is not a requirement under §§ 422.164 and 423.184 to add a measure to the Medicare Part C and D Star Ratings System. CMS reviews measures that are nationally endorsed and in alignment with the private sector, such as measures developed by NCQA and the PQA, for adoption and use in the Star Ratings, and may develop its own measures. CMS has determined that these three PQA-endorsed measures are clinically important and reliable measures, and we proposed to add these three measures to the Star Ratings.

These three measures have been on the display page on *www.cms.gov* since 2021 (2019 measurement year) using MYs as part of the specifications. CMS adapted these measures from the PQA to adjust for partial enrollment by using MYs, however, the PQA's measure specifications have been always based on CE. Therefore, to align more closely with the PQA measure specifications, CMS is updating these measures, making a non-substantive update to use CE instead of MYs during the display period and subsequently will continue to use CE in using these measures (on the display page or as part of the Star Ratings). We described the non-substantive update in the December 2022 proposed rule to provide complete information on the measures we proposed to add to the Star Ratings and discussed the non-substantive updates in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1).

In this section of this rule, we summarize the comments we received on adding the COB, Poly-ACH, and Poly-CNS measures to the Star Ratings, with the non-substantive updates, and provide our responses and final decisions.

Comment: A few commenters strongly supported incorporating the COB and the two Polypharmacy measures to the Star Ratings as these measures are important to address areas of significant risk to beneficiaries. The commenters noted that there is also support in peer-reviewed literature that concurrent use of therapies targeted by these measures should be limited. Additionally, a few commenters supported adding these measures to the Star Ratings since all three were submitted for review by the MUC pre-rulemaking process and were approved by the MAP committees.

Response: We appreciate the support for adding these three measures to the Star Ratings.

Comment: A majority of commenters did not support moving the COB, Poly-ACH, and Poly-CNS measures from the display page to the Star Ratings. Additionally, commenters requested that only one of the two Polypharmacy measures be selected due to overlap of National Drug Codes (NDCs) and medication classes included in the measure specifications. One commenter supported the Poly-CNS over the Poly-ACH measure out of concern for the mental health population and that deprescribing anticholinergics in beneficiaries who have been clinically stable may compromise their health.

Response: We thank the commenters for their feedback. The measures are important areas of focus for the Medicare Part D population from a clinical perspective. The COB measure will help plans identify beneficiaries who have concurrent opioids and benzodiazepine prescriptions since taking these medications concurrently exposes these beneficiaries to high risk of respiratory depression and fatal overdose. According to the Centers for Disease Control and Prevention (CDC) 2022 Clinical Practice Guideline for Prescribing Opioids for Pain (''CDC Guideline''), the CDC recommended that there should be particular caution when prescribing opioid pain medication and benzodiazepine concurrently.[172] We believe that the COB measure is an important and appropriate way to focus on this clinical concern. The PQA Measure Development Team, Stakeholder Advisory Panel, and the American Geriatrics Society (AGS) Beers Criteria Update Panel co-chairs recommended the two separate Polypharmacy measures (the Poly-CNS and Poly-ACH measures) because of different supporting evidence, concurrent use thresholds (three for Poly-CNS and two for Poly-ACH), additive pharmacodynamic effects, and associated clinical outcomes (falls with CNS-active medications and cognitive decline with anticholinergics). The AGS 2019 Updated Beers Criteria provided a strong recommendation based on moderate to high evidence (depending on the drug therapy) to avoid concurrent use of three or more CNS-active medications in older adults because of an increased risk of falls, and for some CNS-active combinations, fractures. Additionally, a study published in JAMA Internal Medicine in 2017, analyzing data from the National Ambulatory Medical Care Survey, demonstrated that CNS polypharmacy in older adult has been trending upward and found that CNS polypharmacy in older adults more than doubled from 2004 to 2013.[173] Furthermore, for the Poly-ACH measure, the updated Beers Criteria provided a strong recommendation based on moderate evidence to avoid concurrent use of two or more anticholinergic medications in older adults because of an increased risk of cognitive decline. A systematic literature review which examined 27 studies from 1966 to 2008 determined that a high burden of anticholinergic use consistently showed a negative association with cognitive performance in older adults.[174] Based on clinical recommendations and supporting evidence, CMS concurs with the PQA, the measure steward, that two separate Polypharmacy measures are appropriate to assess these two areas of focus separately.

We conducted additional data analyses on overlap across the three measures from both medication specification and beneficiary-level perspectives based on public comments we received. We found that the COB and Poly-ACH measures do not have duplicative medication classes or overlapping NDCs. However, the Poly-CNS measure includes medication classes and NDCs that overlap with both the Poly-ACH and COB measures.

Also, we identified Part D beneficiaries who met the numerator inclusion criteria in each of the three measures and evaluated if they had overlapping contract enrollment periods (''enrollment episodes'') across the measures. Note, if a beneficiary has multiple enrollment episodes in the same Part D contract or different contracts, they must meet the numerator criteria separately for each episode. The highest percent of overlapping numerator beneficiary enrollment episodes was between the COB and Poly-CNS measures but below 50 percent (approximately 26.8 percent of the numerator beneficiary enrollment episodes in the COB measure were found in the Poly-CNS measure and 40.9 percent of the numerator beneficiary enrollment episodes in Poly-

[172] CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022 at *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w*.

[173] Maust DT, Gerlach LB, Gibson A, et al. Trends in Central Nervous System-Active Polypharmacy Among Older Adults Seen in Outpatient Care in the United States. JAMA Intern Med. 2017; 177(4):583–585. PMID: 28192559.

[174] Campbell N, Boustani M, Limbil T, et al. The cognitive impact of anticholinergics: a clinical review. Clin Interv Aging. 2009; 4:225–33. PMID: 19554093.

CNS were found in COB). The overlap between the Poly-ACH and Poly-CNS measures' numerators was lower (almost 26.3 percent of the numerator beneficiary enrollment episodes in the Poly-ACH measure were found in the Poly-CNS measure and 9.0 percent were found in Poly-ACH). As expected, the beneficiary overlap was even lower between the COB and Poly-ACH measures because there are no medication overlaps between the two measure specifications, but beneficiaries may meet the numerator inclusion criteria based on their medication regimens (about 2.1 percent of the numerator beneficiary enrollment episodes in the COB measure were found in the Poly-ACH measure and 9.2 percent in Poly-ACH were found in COB).

Based on these comments and data analysis on overlap rates, at this time we are only adding the COB and Poly-ACH measures to the Star Ratings; the Poly-CNS measure will not be added to the Star Ratings at this time due to concerns raised about overlapping medication classes and to monitor for potential duplicative medication therapy classes across the three measures. Because the Poly-CNS measure is a clinically relevant measure for the Part D population, we will retain this measure on the display page. Similar to the Star Ratings, measures on the display page and their numeric measure scores are publicly reported for information purposes. However, unlike the Star Ratings, measures on the display page are not assigned a star and are not associated with QBPs for MA organizations. We may reconsider adding the Poly-CNS to the Star Ratings in the future through rulemaking.

We do not expect a zero-percentage measure rate for these measures as, in some rare cases, it may be medically necessary for beneficiaries to take multiple anticholinergics. Additionally, CMS does not establish a pre-determined threshold to assign stars to these measures and uses the clustering methodology. Therefore, CMS does not have specific cut points or thresholds for performance of Part D contracts in the Star Ratings. Rather, for these measures, contracts are compared based on their contract type and how beneficiaries enrolled in the contracts are taking multiple concurrent prescriptions. In light of the clinical considerations, including the Poly-ACH and the COB measure in the Star Ratings is appropriate as a means to ensure that these important areas of focus are reflected in the overall measure of quality and performance provided by the Star Ratings. We will also share the specification comments with the PQA, the measure steward.

Comment: A few commenters were concerned that these measures pose similar challenges as the retired Star Ratings High Risk Medication (HRM) measure, and addition of the measures to the Star Ratings may lead to tighter utilization management (UM) and safety edits that could result in additional administrative burden to prescribers, pharmacists, and beneficiaries or access issues or disruption of therapy for beneficiaries. Commenters recognized the measures' importance but were concerned with prescriber burden. Additionally, commenters believed that other policies in the Part D program to address these areas of concern already exist, such as Drug Management Programs (DMPs), concurrent drug utilization review and point-of-sale (POS) edits, MTM programs, and UM such as prior authorizations.

Response: We strongly believe that the COB, Poly-CNS, and Poly-ACH measures are important measures that address specific clinical risks in the Medicare Part D population. We do not anticipate that there will be increased workload for plans or providers due to adding any of these measures to the Star Ratings. These measures are not new and have been on display page since 2021 (using data from the 2019 measurement year); therefore, plans, providers, and beneficiaries are familiar and experienced with these measures. The long-term benefits of improved medication safety, reduce medication errors, and better patient outcomes significantly outweigh some potential burden associated with efforts to address over-utilization. Additionally, we understand that use of these medications may be medically necessary for some beneficiaries 65 and older, and as noted in the response earlier in this section of the preamble, CMS does not expect a zero-percentage rate in the COB, Poly-CNS, or Poly-ACH measures. As demonstrated in the annual data included in the December 2022 proposed rule (87 FR 79619), the rates are decreasing for all three measures, suggesting improvement is occurring.

Furthermore, these three measures are not duplicative of existing policies in Part D which are complementary tools to target specific types of concurrent use of medications among Medicare Part D enrollees and drive quality improvement. The COB and Polypharmacy measures are intended as retrospective plan performance measures; concurrent drug utilization reviews, as required under § 423.153(c)(2), and opioid safety edits are reviews at POS to proactively engage beneficiaries and prescribers to address prescription opioid overuse; DMPs are required statutorily in section 1860D–4(c)(5)(A) of the Act for plans to monitor beneficiaries who are at-risk for misuse or abuse of frequently abused drugs. Frequently abused drug, as defined at 42 CFR 423.100, is a controlled substance that the Secretary determines, based on several factors, is frequently abused or diverted. CMS has determined that opioids (except buprenorphine for opioid use disorder and injectables) and benzodiazepines are frequently abused drugs for purposes of Part D DMPs. MTM helps beneficiaries and their caregivers improve their medication use and optimize therapeutic outcomes.

As a reminder, sponsors may apply UM controls to reduce inappropriate use of concurrent therapies. UM controls must be submitted and approved by CMS through HPMS formulary submissions, unless they are POS safety related edits that can be implemented without submission or approval by CMS pertaining to duplicative therapy or when FDA labeling clearly indicates the dispensing is unsafe, duplicative, or contraindicated, such as edits regarding specific age-related contraindications. Edits based upon warnings and precautions in the label, as opposed to contraindications or doses that exceed those supported by the label, must be submitted to CMS for approval. Sponsors that implement unapproved edits for these medications may be found to have data integrity issues. Per §§ 422.164(g) and 423.184(g), CMS may reduce a contract's measure rating to 1 star for concerns such as data inaccuracies, partiality, or incompleteness. Such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s). Implementation of unapproved edits for these measures may bias sponsors' PDE data used for these measures and thus be subject to this policy. Inclusion of polypharmacy medications in the measures is not a contraindication to use, but rather an opportunity to evaluate the use of concurrent polypharmacy medications in Medicare Part D beneficiaries 65 years and older.

Comment: Some commenters requested that CMS delay adding these measures to the Star Ratings by at least 2 years to provide sponsors additional time to prepare for the transition because it may be difficult to improve

the measures or incentivize prescribers and to minimize unnecessary disruptions in therapy.

Response: Sponsors were given advance notice that CMS planned rulemaking to add these measures to the Star Ratings in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, which was released in April 2019. Per § 423.184(c)(3), new Part D measures are posted on the display page for at least 2 years prior to becoming a Star Ratings measure. Sponsors have been on notice for more than 4 years that these measures could be added to the Star Ratings, and all three measures have been on the display page since 2021 (2019 measurement year). We are finalizing the adoption of the COB and Poly-ACH measures beginning with the 2025 measurement period for the 2027 Star Ratings. Part D plans have had sufficient time to gain experience with these measures and to prepare for these measures to be added to the Star Ratings.

Comment: Commenters requested that CMS add socio-demographic status (SDS) risk-adjustment to the COB and Polypharmacy measures because Medicare Advantage organizations, in particular those that offer dual eligible or special needs plans, will be disproportionately affected as these plans enroll a greater number of complex patients with mental health conditions or disabilities.

Response: Currently these measures have not been tested for SDS risk-adjustment because the Poly-ACH, Poly-CNS, and COB measures are process measures and are not recommended for SDS risk adjustment by the PQA. We will share this comment with the PQA, the measure steward.

Comment: Some commenters opposed the COB and Poly-CNS measures because they believe these measures contradict the updated CDC 2022 Clinical Practice Guideline for Prescribing Opioids for Pain. These commenters noted that the CDC Guideline discourages including inflexible dose thresholds in policies involving opioid pain medications.

Response: The COB and Poly-CNS measure specifications do not contradict the CDC Guideline [175] which recommends particular caution when prescribing opioid pain medication and benzodiazepines concurrently and that prescribers should consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. These measures do not include dosage thresholds in the measure specifications and are not intended to guide clinical-decision-making for individual patients, but rather, these measures evaluate the use of concurrent therapies.

For the COB and Polypharmacy measures, since there are no dosage thresholds, a beneficiary would be potentially eligible for the COB and polypharmacy measures once they have overlapping days supply for concurrent use of unique target medications included in these measures. Specifically, the COB measure evaluates the percentage of beneficiaries 18 years of age or greater with concurrent use of prescription opioids and benzodiazepines. The COB numerator is defined as the number of beneficiaries from the denominator with 2 or more prescription claims for any benzodiazepines with different dates of service and concurrent use of opioids and benzodiazepines for 30 or more cumulative days. The COB denominator is defined as beneficiaries with 2 or more prescription claims for opioid prescriptions on different dates of service and with 15 or more cumulative days' supply during the measurement year. The Poly-CNS measure evaluates the percentage of beneficiaries 65 years of age or older with concurrent use of 3 or more unique CNS-active medications. The numerator is defined as the number of beneficiaries from the denominator with concurrent use of 30 or more cumulative days of 3 or more unique CNS-active medications, each with 2 or more prescription claims on different dates of service during the measurement year. The denominator is defined as beneficiaries with 2 or more prescription claims for the same CNS-active medication on different dates of service during the measurement year.

Comment: Commenters requested that CMS expand exclusions for both Polypharmacy measures to include diagnoses of significant mental health (such as schizophrenia or bipolar disorder) since these conditions are typically treated with multiple antipsychotics, anti-depressants, and/or anti-epileptics. Commenters noted that these measures may have limited benefits to beneficiaries with Alzheimer's disease and dementia, recommended that CMS consider extending overlap days to at least 120 days or more to ensure that plans and providers can work collaboratively in developing realistic plans around deprescribing, and recommended that CMS consider dosage reduction or tapering therapy of concurrent anticholinergic medications. Another commenter recommended excluding benzodiazepine prescriptions that are less than 5 days' supply due to a procedure for the COB measure. Commenters requested that long-term care (LTC) residents be excluded from the COB measure since benzodiazepines are used in the LTC population to treat anxiety or used as a muscle relaxant which could result in delay in therapy. Furthermore, a commenter noted that concomitant use of opioids and benzodiazepines are closely monitored in LTC facilities. Additionally, a commenter suggested that CMS consider dosages of concurrent anticholinergic medications and their overall anticholinergic potential, as opposed to a count of medications, before identifying members for potential overprescribing since beneficiaries with severe mental illnesses may be using multiple antipsychotics, or anti-depressants, and/or anti-epileptics.

Response: We appreciate the commenters' feedback. As a reminder, both Polypharmacy measures exclude beneficiaries in hospice care. Additionally, beneficiaries with a seizure disorder diagnosis during the measurement year are excluded from the Poly-CNS measure. The current exclusions for the COB measure are beneficiaries in hospice care, with a cancer diagnosis, with sickle cell disease diagnosis, and in palliative care during the measurement year. Older adults with co-occurring mental health disorders and multiple anticholinergic medications face an elevated risk of adverse consequences, particularly cognitive decline, increased fall risks, and central nervous system side effects. Continuous monitoring of these individuals is crucial for early detection, medication optimization, and quality of life improvement. Studies have demonstrated positive outcomes when healthcare providers implemented routine anticholinergic burden assessment and medication-switching interventions; these findings underscore the critical need for continuous monitoring and proactive management of the anticholinergic burden in this vulnerable population.[176] [177] [178]

[175] Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioid for Pain—United States, 2022 at *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

[176] Eum, S., Hill, S.K., Rubin, L.H., Carnahan, R.M., Reilly, J.L., Ivleva, E.I., . . . & Bishop, J.R. (2017). Cognitive burden of anticholinergic medications in psychotic disorders. Schizophrenia research, 190, 129–135.

[177] Lupu, A.M., Clinebell, K., Gannon, J.M., Ellison, J.C., & Chengappa, K.R. (2017). Reducing anticholinergic medication burden in patients with psychotic or bipolar disorders. The Journal of Clinical Psychiatry, 78(9), 17141.

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Therefore, CMS will apply the measure specifications as intended by PQA, the measure steward. PQA employs a highly rigorous and transparent process for developing and endorsing quality measures. This multi-phase lifecycle involves several crucial phases like measure conceptualization, specification, testing, endorsement, and implementation and maintenance. In the final implementation and maintenance stage, endorsed measures are reviewed and updated periodically to reflect evolving practice standards and data availability. This ongoing process ensures that measures remain clinically relevant and valid.

We will share measure specification comments for expanding the exclusions and the methodology considerations with the PQA, the measure steward for the COB and polypharmacy measures.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the addition of the Poly-ACH and COB measures in the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings. The Poly-CNS measure will remain on the display page and not be added to the Star Ratings.

In addition, we announced the non-substantive updates to the Poly-CNS, Poly-ACH, and COB measures to align with the PQA measure specifications to use CE and no longer adjust for MYs in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1). CMS will make the update to change from MYs to CE for the 2024 measurement year for all three measures. The Poly-ACH and COB measures will be added to the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings with these updates.

4. Summary of Measure Changes for the Part C and D Star Ratings

Table VII.1 summarizes the additional and updated measures addressed in this final rule, beginning with the 2027 Star Ratings. The measure descriptions listed in this table are high-level descriptions. The annual Star Ratings measure specifications supporting document, the *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 2027 are produced in the fall of 2026. If a measurement period is listed as ''the calendar year 2 years prior to the Star Ratings year'' and the Star Ratings year is 2027, the measurement period is referencing the January 1, 2025 to December 31, 2025 period.

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[178] Mukku, S.S., Sinha, P., Sivakumar, P.T., & Varghese, M. (2021). Anticholinergic burden among hospitalised older adults with psychiatric illnesses—a retrospective study. Current Drug Safety, 16(3), 264–271.

Table VII.1. Summary of New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2025

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	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	00139-02-C-PARTC	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	00109-01-C-PARTC	Clustering	Special Needs Plans
Part D Measures								
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		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		Clustering	MA-PD and PDP
Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)**	The percent of MTM program enrollees, 18 years or older, who received a CMR during the reporting period.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting Requirements	The calendar year 2 years prior to the Star Ratings year	00454-01-C-PARTD	Clustering	MA-PD and PDP

*Revised Measures

** Effective for the 2027 measurement year.

C. Revising the Rule for Non-Substantive Measure Updates (§§ 422.164(d) and 423.184(d))

We proposed 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. This proposal was only adding another example to the non-exhaustive list of non-substantive measure changes that the current regulations permit to be done through the Advance Notice/Rate Announcement process. For example, as described in the CY 2024 Rate Announcement, we are implementing the web-based mode (as an addition to the current mixed mode protocol) for the 2024 Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey implementation used for the 2025 Star Ratings. 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 when §§ 422.164(d) and 423.184(d) were initially adopted, 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 proposed 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, adding a web mode of survey administration to the current survey administration of mail with telephone follow-up of non-respondents to the mail survey that historically has been used for CAHPS and Health Outcomes Survey (HOS) would not change what is being measured, but would only expand the way the data can be collected. Therefore, that is a non-substantive update to the measures.

We proposed 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 solicited comments on this proposal.

Comment: We received several comments supporting the proposal to revise regulation text by adding a new mode of data collection as another example of a non-substantive change.

Response: CMS thanks the commenters for their support.

Comment: We received a few comments opposed to this proposal. Commenters stated that a new mode of data collection should be considered a substantive change. A couple of commenters were concerned a change in survey modality would produce different survey results and that survey modality preferences differ by age groups, which may affect the population responding. A commenter expressed concerned that web-based respondents could create a source of bias in the data due to differences in socioeconomic factors, plan type, or geography and could impact contract performance.

Response: CMS disagrees that changes to expand modes of data collection would be a substantive change to a measure. Notwithstanding an expansion of the modes of data collection, the denominator will remain the same. Expanding the modes of data collection will generally result in more data regarding performance on the measure. As a result, the measure will better reflect actual performance of the organization and provide more information to CMS and the public.

For example, for the survey administration for CAHPS and HOS measures used as the example in the proposed rule, the denominator for the measures continues to include plan enrollees. The addition of web surveys to the mail-phone survey protocol in no way changes the numerator or denominator of the measure. Further, our study of using web surveys as well as mail-phone surveys did not indicate any significant change in the resulting data or measure scores, consistent with other studies.[179] The CAHPS survey measures and results are unchanged as a result of our proposed change to add a new mode of data collection as a non-substantive change. In the field test, a majority of respondents in the web-mail-phone protocol still chose to respond by mail or phone. Among respondents with an available email address, 79 percent chose to respond by mail or phone. Further, the composition of respondents is similar in the web-mail-phone and mail-phone protocols. We compared respondents to the web-mail-phone and mail-phone protocols by age, sex, receipt of a low-income subsidy or dual eligible status (LIS/DE), race/ethnicity, education, and health status, and found that respondents were quite similar; the overall pattern of differences was consistent with chance.

The use of a three-phase sequential multimode approach, web followed by mail followed by telephone, allows MA enrollees choices about how to respond. It maintains or increases response rates for all groups of MA enrollees and is available to those with or without broadband or telephone access. While the increases in response rates vary slightly by enrollee characteristics, this does not create bias, as scores from those randomized for the web-mail-phone protocol were similar to those randomized for the mail-phone protocol in our field test. Of 39 items compared between the web-mail-phone and mail-phone protocols, none differed in case-mix adjusted mean score at $p<0.01$ and only two differed at $p<0.05$, a pattern consistent with chance. Thus, there is no evidence of a mode effect on scores from the web-mail-phone protocol relative to the mail-phone protocol.

While different plan rates of email availability may influence response rates gains, they do not bias plan scores because response by web results in scores similar to those obtained under the mail-phone protocol. Similarly, no overall effect on scores over time is anticipated with the addition of the web mode.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the clarification to the regulation text at §§ 422.164(d)(1)(v) and 423.184(d)(1)(v). As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and for measures in the 2025 Star Ratings where CMS has complied with §§ 422.164(d)(1) and 423.184(d)(1) in adopting the non-substantive change.

D. Weight of Measures With Substantive Updates (§§ 422.166(e)(2) and 423.186(e)(2))

We proposed 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 when these regulations were first adopted, 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 proposed 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 provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In the second and subsequent years after the measure returns to the Star Ratings after being on the display page with a substantive update, the measure would be assigned the weight associated with its category, which is what happens with new measures as

[179] For example, Fowler FJ, Cosenza C, Cripps LA, Edgman-Levitan S, Cleary PD. The effect of administration mode on CAHPS survey response rates and results: A comparison of mail and web-based approaches. *Health Serv Res.* 2019; 54: 714–721. *https://doi.org/10.1111/1475-6773.13109.*

well. In addition, we proposed to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We solicited comments on this proposal.

Comment: All commenters supported the proposal to clarify how we treat measures with substantive updates when they return to the Star Ratings program. Some commenters noted that this proposal would result in a phase-in approach reducing potential volatility, and it provides plans sufficient notice to familiarize themselves with a measure's updated specifications, assess potential impacts, and incorporate changes to internal processes if needed. A commenter requested CMS confirm that when the three Part D medication adherence measures return to the Star Ratings after adding risk adjustment for sociodemographic status, they will each have a weight of 1 for the first year.

Response: We appreciate the commenters' support. In the April 2023 final rule, CMS finalized the substantive update to the three medication adherence measures for the 2028 Star Ratings (2026 measurement year). The first year (2028 Star Ratings) the updated medication adherence measures will be in the Star Ratings they will have a weight of 1, but then beginning with the following Star Ratings year, the weight will increase to 3, as these measures are categorized as intermediate outcome measures.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the additional language added to §§ 422.166(e)(2) and 423.186(e)(2) with a slight clarification that in subsequent years, a new or substantively updated measure will be assigned the weight associated with its category, and we are finalizing the update to the heading for paragraph (e)(2). As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and to the 2025 Star Ratings.

E. Data Integrity (§§ 422.164(g) and 423.184(g))

We currently have rules specified at §§ 422.164(g) and 423.184(g) to reduce a measure rating when CMS determines that a contract's measure data are incomplete, inaccurate, or biased. For the Part C appeals measures, we have statistical criteria to reduce a contract's appeals measures for missing Independent Review Entity (IRE) data. Specifically, these criteria allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. See 83 FR 16562 through 16564. The data underlying a measure score and Star Rating must be complete, accurate, and unbiased for them to be useful for the purposes we have codified at §§ 422.160(b) and 423.180(b). In the April 2018 final rule (83 FR 16562), CMS codified at §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii) a policy to make scaled reductions to the Part C and D appeals measures' Star Ratings when the relevant IRE data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. Following the process in § 423.184(e)(2) and for the reason specified in § 423.184(e)(1)(ii), we removed the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) beginning with the 2020 measurement year and 2022 Star Ratings in the 2020 Rate Announcement [180] due to low statistical reliability; thus, the scaled reductions are no longer applicable to the Part D appeals measures. However, we made no changes to the scaled reductions used with the Part C appeals measures, Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions, because there were no similar statistical reliability issues with those measures. Therefore, these two Part C measures continue to be subject to the scaled reductions authorized at § 422.164(g)(1)(iii) based on TMP or audit information.

Because the Part D appeals measures are no longer part of the Star Ratings, we proposed to remove and reserve the paragraphs at §§ 422.164(g)(1)(iii)(B), (1)(iii)(F), (1)(iii)(I), and 423.184(g)(1)(ii). Paragraphs (B), (F), and (I) of § 422.164(g)(1)(iii) all address how the error rate on the TMP for the Part D appeals measures had been used in calculating scaled reductions for MA–PDs that are measured on both Part C and Part D appeals. Currently, § 423.184(g)(1)(ii) addresses the scaled reductions for Part D appeals measures based on the TMP. Given the removal of the Part D appeals measures from the Star Ratings, these provisions are moot. We proposed to reserve the relevant paragraphs to avoid the risk that redesignating the remaining paragraphs would cause unintended consequences with any existing references to these provisions.

The completeness of the IRE data is critical to support fair and accurate measurement of the two Part C appeals measures. Since the 2019 Star Ratings we have used data from the TMP, which uses the Part C audit protocols for collecting Organization Determinations, Appeals and Grievances (ODAG) universes, to determine whether the IRE data used to calculate the Part C appeals measures are complete. As described at § 422.164(g)(iii), we use scaled reductions to account for the degree to which the IRE data are missing. The current regulations describe how scaled reductions are based on the TMP. However, due to a change in the Part C audit protocols for collecting universes of ODAG data, we proposed to modify, and in one case reserve, paragraphs (g)(1)(iii), (g)(1)(iii)(A)(*1*) and (*2*), (g)(1)(iii)(H), (g)(1)(iii)(J), (g)(1)(iii)(K)(*2*), and (g)(1)(iii)(O) to change how we address reductions in the Star Ratings for Part C appeals measures using different data. We proposed to revise the introductory language in § 422.164(g)(1)(iii) to remove references to the timeliness monitoring study and audits and replace them with references to data from MA organizations, the IRE, or CMS administrative sources. In addition, our proposed revisions to this paragraph included minor grammatical changes to the verb tense. We also proposed to modify § 422.164(g)(1)(iii)(A) to use data from MA organizations, the IRE, or CMS administrative sources to determine the completeness of the data at the IRE for the Part C appeals measures starting with the 2025 measurement year and the 2027 Star Ratings. Currently, data collected through § 422.516(a) could be used to confirm the completeness of the IRE data; however, data collected from MA organizations through other mechanisms in addition to data from the IRE or CMS administrative sources could be used in the future. The proposed amendment to § 422.164(g)(1)(iii)(A) was not intended to limit the data CMS uses to conduct analyses of the completeness of the IRE data in order to adapt to changing information submissions that could be reliably used for the same purpose in the future. The revisions proposed for the other paragraphs provided for a new calculation to implement scaled reductions for the Part C appeals measures for specific data integrity issues.

Part C contracts are required to send partially favorable (partially adverse) and unfavorable (adverse) decisions to the IRE within applicable timeframes as specified at § 422.590(a) through (e). In order for the existing Part C appeals measures (Plan Makes Timely Decisions

[180] Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (*cms.gov*).

about Appeals and Reviewing Appeals Decisions) to accurately reflect plan performances in those areas, the appeals must be sent to the IRE because the data source for these measures is based on the data that have been submitted to the IRE. Currently, through the Part C Reporting Requirements established under § 422.516(a), CMS collects information at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of unfavorable claims and the number of unfavorable service requests by enrollees/representatives and non-contract providers) over a calendar year.[181] These data are subject to data validation requirements, in accordance with specifications developed by CMS, under § 422.516(g), to confirm that they are reliable, valid, complete, and comparable. CMS would use this information to determine the total number of cases that should have been sent to the IRE over the measurement year (that is, number of partially favorable reconsiderations + number of unfavorable reconsiderations) to compare to information from the IRE about submissions received from each MA organization. In the future, CMS may use detailed beneficiary-level data collected on the number of partially favorable reconsiderations and the number of unfavorable reconsiderations if such more detailed information is collected under CMS's statutory and regulatory authority to require reporting and data submission from MA organizations (such as the reporting requirements in §§ 422.504(f)(2) and/or 422.516(a)).

To determine if a contract may be subject to a potential reduction for the Part C appeals measures' Star Ratings, we proposed to compare the total number of appeals received by the IRE that were supposed to be sent to the IRE per regulations as specified at § 422.590(a) through (e) and (g) (which are explained in guidance at section 50.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance [182]), including all appeals regardless of their disposition (for example, including appeals that are dismissed or withdrawn), to the total number of appeals that were supposed to go to the IRE. The total number of appeals that were supposed to be sent to the IRE would be based on the sum of the number of partially favorable reconsiderations and the number of unfavorable reconsiderations from the Part C Reporting Requirements during the measurement year (January 1st to December 31st). We proposed to modify the calculation of the error rate at § 422.164(g)(1)(iii)(H) by taking 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that were supposed to be sent to the IRE (Equation 1). The total number of appeals that were supposed to be sent to the IRE in Equation 2 would be calculated from the data described in the revisions to § 422.164(g)(1)(iii)(A):

Equation (1)

Equation (1)

$$Part\ C\ Calculated\ Error\ Rate = 1 - \frac{Total\ number\ of\ cases\ received\ by\ the\ IRE}{Total\ number\ of\ cases\ that\ should\ have\ been\ forwarded\ to\ the\ IRE}$$

Equation (2)

Total Number of Cases that should have been forwarded to the IRE = Number of partially favorable reconsiderations + Number of unfavorable reconsiderations

We proposed to remove and reserve § 422.164(g)(1)(iii)(J) because we intend to calculate the Part C error rate based on 12 months rather than a projected number of cases not forwarded to the IRE in a 3-month period as has historically been done with the TMP data. Currently, a contract is subject to a possible reduction due to lack of IRE data completeness if the calculated error rate is 20 percent or more and the projected number of cases not forwarded to the IRE is at least 10 in a 3-month period as described at § 422.164(g)(1)(iii)(K). We proposed to modify § 422.164(g)(1)(iii)(K)(*2*) so that the number of cases not forwarded to the IRE is at least 10 for the measurement year (that is, total number of cases that should have been forwarded to the IRE minus the total number of cases received by the IRE is at least 10 for the measurement year). The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions specified in paragraph (K), the contract would not be subject to reductions for IRE data completeness issues.

We proposed at § 422.164(g)(1)(iii)(O) that the two Part C appeals measure Star Ratings be reduced to 1 star if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures. For example, the data collected in the Part C Reporting Requirements go through a data validation process (§ 422.516(a)). CMS has developed and implemented data validation standards to ensure that data reported by sponsoring organizations pursuant to § 422.516 satisfy the regulatory obligation. If these data are used to validate the completeness of the IRE data used to calculate the Part C appeals measures, we would reduce the two Part C appeals measure Star Ratings to 1 star if a contract fails data validation of the applicable Part C Reporting Requirements sections for reconsiderations by not scoring at least 95 percent or is not compliant with data validation standards (which includes sub-standards as applicable), since we cannot confirm the data used for the Part C appeals measures are complete.

We also proposed to update § 422.164(g)(1)(iii)(A)(*2*) to change the data source in the case of contract consolidations so that the data described in paragraph (g)(1)(iii)(A)(*1*) are combined for consumed and surviving contracts for the first year after consolidation. In addition, we proposed to delete the phrase ''For contract consolidations approved on or after January 1, 2022'' as unnecessary.

We did not propose to update the steps currently described at § 422.164(g)(1)(iii)(C), (D), (E), (G), K(*1*), (L), (M), and (N) to determine whether a scaled reduction should be applied to the two Part C appeals measures. We welcomed feedback on this updated approach for making scaled reductions

[181] In the Medicare Part C Technical Specifications Document for Contract Year 2023, elements E through L in Subsection #4 on page 15 are currently used to identify unfavorable and partially favorable reconsiderations (*https://www.cms.gov/files/document/cy2023-part--technical-specifications-222023.pdf*).

[182] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

proposed at § 422.164(g)(1)(iii), (1)(iii)(A)(*1*) and (*2*), (1)(iii)(H), (1)(iii)(K)(*2*), and (1)(iii)(O), the removal of the Part D related provisions at § 422.164(g)(1)(iii)(B), (1)(iii)(F), and (1)(iii)(I), and § 423.184(g)(1)(ii), and removal of the provision at § 422.164(g)(1)(iii)(J), and we received several comments. A discussion of these comments, along with our responses follows.

Comment: We received a number of comments in support of our proposal to update the methodology for applying scaled reductions for the Part C appeals measures. A couple of commenters expressed strong support for this update, because it will help ensure data integrity by discouraging MA plans from not sending required appeals to the IRE to earn higher Star Ratings.

Response: CMS appreciates the support of the update to the methodology for applying scaled reductions for the Part C appeals measures. Given the financial and marketing incentives associated with higher performance in Star Ratings, CMS agrees that safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.

Comment: A few commenters asked for clarifications about the types of cases that CMS is reviewing for the scaled reductions and the types of cases that need to be sent to the IRE. A commenter asked if it was CMS's intent to send all favorable cases to the IRE.

Response: We are only examining the appeals that are currently required to be sent to the IRE. Part C contracts are required to send partially favorable (partially adverse) and unfavorable (adverse) decisions to the IRE within applicable timeframes as specified at § 422.590(a) through (e) and (g). (88 FR 78560). It is not CMS's intent for plans to send all favorable cases (from the plan level) to the IRE.

CMS has also addressed and explained the obligation of an MA plan to send cases to the IRE in current Medicare guidance in the *Parts C & D Enrollee Grievances, Organization/ Coverage Determinations, and Appeals Guidance: Effect of Failure to Meet the Timeframe for Level 1 Appeals.*[183] If a plan fails to provide the enrollee with a level 1 appeal decision within the required timeframes, this failure constitutes an adverse decision. In this case, the plan must forward the complete case file to the IRE pursuant to § 422.590(d) and (g). See also section 50.12.1 regarding forwarding adverse level 1 appeals to the IRE. CMS guidance also permits an exception to this when a plan makes a fully favorable determination on a level 1 appeal less than 24 hours after the end of the adjudication timeframe and effectuates the favorable determination. In this case, the plan should consider effectuating and notifying the enrollee of the favorable appeal decision in lieu of forwarding the appeal to the IRE.

For the updates to the scaled reductions methodology, which we are finalizing as proposed with one clarification, we are examining all cases that were sent to the IRE that should have been sent versus the ones that were supposed to be sent per regulation and guidance. The denominator would include the number of level 1 appeals where the plan made an unfavorable or partially favorable decision for the appeal. The numerator would include all the cases that the IRE received regardless of the disposition the IRE subsequently gave the case (*i.e.,* unfavorable (upheld); favorable (overturn), partially favorable (partially overturn), received by but not evaluated by the IRE because the MA plan approved coverage or dismissed). We are adopting additional language at § 422.164(g)(1)(iii)(H) to clarify that the numerator is the total number of cases received by the IRE that should have been sent.

Comment: A commenter asked for clarification on how a negative error rate would be treated, noting that would be possible since CMS is reviewing all cases regardless of disposition.

Response: CMS clarifies that there cannot be a negative error rate unless a plan sends cases to the IRE that they should not be sending. CMS is comparing all cases sent to the IRE relative to all cases that should have been sent to the IRE. We are adding language at § 422.164(g)(1)(iii)(H) to clarify that the numerator is the total number of cases received by the IRE that were supposed to be sent to the IRE. The denominator remains the number of cases that should have been forwarded to the IRE.

Comment: A commenter recommended that CMS reconsider the inclusion of dismissed appeals, noting that such appeals are dismissed due to a variety of reasons and inclusion in the Star Ratings may inappropriately impact performance. A couple of commenters asked for clarification on what other kinds of dismissals would be included. They noted that CMS proposes the total number of cases received by the IRE would include all appeals regardless of their disposition and gives the example of appeals dismissed for reasons other than the plan's agreement to cover disputed services.

Response: There are no changes to the current Part C appeals measures and which appeals are included. The proposed methodology to apply scaled reductions is a mechanism to ensure that the data used for evaluating performance for these measures are accurate, complete, and unbiased. Through this methodology, we are determining if all of the cases that should have been sent to IRE were sent. For the Plan Makes Timely Decisions about Appeals (Part C) measure, the denominator includes unfavorable (upheld) appeals, favorable (overturned) appeals, partially favorable (partially overturned) appeals, and appeals received by but not evaluated by the IRE because the MA plan approved coverage. The Reviewing Appeals Decisions (Part C) measure excludes dismissed and withdrawn appeals and appeals received but not evaluated by the IRE because the MA plan approved coverage.

As a reminder, Part C sponsors are required to send all adverse or partially adverse cases to the IRE. In some cases, the IRE could dismiss the appeal or the appeal (that is, reconsideration request) could be withdrawn after the appeal is sent to the IRE. Cases may be dismissed for a variety of reasons under § 422.590(d). For example, if the enrollee requested a pre-service appeal but then passes away before the appeal process is complete, the case is dismissed. If a plan processed an appeal, but the plan should not have because a proper party did not file the appeal request, such as an individual who is not the enrollee and who does not have a valid power of attorney or appointment of representation form, the IRE will also dismiss it. Cases can be withdrawn when the appellant contacts the IRE directly and advises them that they no longer wish to proceed with their appeal.

Comment: A few commenters recommended a transition year so Part C sponsors can get used to the new approach for scaled reductions. A commenter wanted additional time since they suggested that plans may need to put in additional efforts to ensure that they pass data validation for the Part C Reporting Requirements.

Response: Part C sponsors currently collect and submit to CMS the data that would be used for the scaled reductions through the Part C Reporting Requirements established by CMS under § 422.516(a). CMS does not believe that a transition year is needed since we

[183] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

would be using existing data collected at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of unfavorable claims and the number of unfavorable service requests by enrollees/representatives and non-contract providers) over the measurement year. (Partially favorable and unfavorable reconsiderations must all be forwarded to the IRE.) In the future, we noted in the proposed rule that alternative data sources could be used that collect similar information. To help in the transition to the updated methodology, CMS will add information to HPMS for the 2026 Star Ratings to provide information about the scaled reductions that would have been applied if this methodology was in place for that year. This information most likely will be posted in HPMS following the release of the 2026 Star Ratings plan previews.

Comment: A few commenters questioned whether CMS expected plans to achieve a 95 percent or greater accuracy rate. A commenter was concerned this would impact smaller plans more.

Response: CMS did not propose to use a 95 percent error rate as part of the scaled reductions implemented pursuant to § 422.164(g)(1)(iii). We did not propose any changes to the error rates at § 422.164(g)(1)(iii)(D) to determine the size of the scaled reductions. The thresholds used for determining the reduction are now and will continue to be under this revision to § 422.164(g)(1)(iii), as follows: (1) 20 percent, 1 star reduction; (2) 40 percent, 2-star reduction; (3) 60 percent, 3-star reduction; and (4) 80 percent, 4 star reduction. However, these scaled reductions are specific to the evaluation of missing cases that have not been forwarded to the IRE when they should have been for calculation of the appeals measures.

Per § 422.164(g)(1)(ii), CMS has a different downgrade policy for Star Ratings measures based on whether the data that an MA organization must submit to CMS under § 422.516 do not pass data validation. Since we will use data submitted under § 422.516 to evaluate data completeness of the cases submitted to the IRE for the Part C appeals measures, we will use similar rules to evaluate the quality of the appeals information submitted that is used to determine data completeness of the Part C appeal measures that is described at § 422.164(g)(1)(iii)(O).

Per § 422.164(g)(1)(ii) (which we did not propose to amend and are not revising in this final rule), if a contract fails data validation of the applicable Part C Reporting Requirements sections (that is, the reporting required under § 422.516) for reconsiderations by not scoring at least 95 percent or is not compliant with data validation standards, we proposed to reduce the appeals measures' Star Ratings to 1 star. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are inaccurate, incomplete, or biased. The validation score of 95 percent on Part C and Part D Reporting Requirements is an existing data integrity policy that applies to other measures. CMS finalized these data integrity policies at §§ 422.164(g)(1)(ii) and 423.184(g)(1)(i) to distinguish between occasional errors and systematic issues. (see *83 FR 16562*) Currently, the two Star Ratings measures based on Part C and D Reporting Requirements data (SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) (Part D)) are calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Per the Part C and D Star Ratings Technical Notes, contracts that do not score at least 95 percent on data validation for these reporting sections and/or were not compliant with data validation standards/sub-standards for at least one of the data elements used to calculate the measures are not rated in these measures, and the contract's measure score is reduced to 1 star. CMS has relied on the Part C and D Reporting Requirements data validation audit to confirm the integrity of these plan-reported data since these two measures were first added to the Star Ratings program.

Since we will be using the Part C Reporting Requirements data to calculate scaled reductions, we proposed to reduce the Part C appeals measures to 1 star if we do not have data that passed the Part C Reporting Requirements data validation audit to validate the data completeness of these measures. Plan size should not affect accuracy of data validation for the reporting sections. Additionally, as established under §§ 422.164(g)(2) and 423.184(g)(2), CMS can reduce a measure Star Rating to 1 for additional issues related to data accuracy not described in §§ 422.164(g)(1)(i) through (iii) or 423.184(g)(1)(i).

Comment: A commenter opposed the change in timeframe from a 3-month period to the measurement year because they believe without a change in the case minimum it would increase the burden on contracts, particularly low-volume contracts. Another commenter strongly supports the change to a 12-month period since it aligns with the measurement period for the measure.

Response: CMS does not agree that the proposed scaled reductions methodology would increase the burden to contracts, and we appreciate the support for the 12-month timeframe. CMS is planning to use data that are already provided by MA organizations and available to CMS. The data from the current Part C Reporting Requirements established under § 422.516 would be used to calculate the scaled reductions; therefore, there is no increased burden for sponsors. The proposed timeframe of 12 months more accurately aligns with the measurement period for both Part C appeals measures. We exclude from the scaled reductions contracts that have 10 or fewer cases that should have been forwarded to the IRE and were not during the measurement year to address statistical concerns with precision. Increasing this number to greater than 10 cases would create incentives for contracts not to forward cases to the IRE that they should be forwarding.

Comment: A commenter asked whether the TMP data will continue to be leveraged to determine data completeness and calculate the scaled reductions for the Part C appeals measures.

Response: The TMP data will no longer be used for determining scaled reductions of the Part C appeals measures.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed this updated approach for making scaled reductions at § 422.164(g)(1)(iii), (1)(iii)(A)(*1*) and (*2*), (1)(iii)(H), (1)(iii)(K)(*2*), and (1)(iii)(O) for the 2027 Star Ratings (2025 measurement year) with a modification to clarify that the numerator is the total number of cases received by the IRE that should have been sent at § 422.164(g)(1)(iii)(H). We are finalizing the removal of the Part D related provisions at § 422.164(g)(1)(iii)(B), (1)(iii)(F), and (1)(iii)(I), and § 423.184(g)(1)(ii), and the removal of the provision at § 422.164(g)(1)(iii)(J) without modification.

F. Review of Sponsor's Data (§§ 422.164(h) and 423.184(h))

Currently, §§ 422.164(h) and 423.184(h) provide that an MA organization (and a cost plan organization as the regulations are applied under § 417.472(k)) and a Part D plan sponsor may request a review of certain administrative data (that is, the contracts' appeals data and Complaints Tracking Module data) before Star Ratings are calculated. The regulations provide for CMS to establish an annual deadline by which such requests must be submitted. In the November 2023 proposed rule, CMS proposed to expand the policy for requests that CMS review certain data used for Star Ratings to include administrative data used for their contract's Part D Star Rating Patient Safety measures by adding new §§ 422.164(h)(3) and 423.184(h)(3). These requests would also have to be received by the annual deadline set by CMS. We intended that the requests could include CMS's review of PDE, diagnosis code, and enrollment data that are used for the Part D Star Rating Patient Safety measures, but the requests are not necessarily limited to these specific data.

CMS reports and updates the rates for the current Part D Star Ratings Patient Safety measures (that is, Medication Adherence for Cholesterol (Statins) (ADH-Statins), Medication Adherence for Hypertension (RAS Antagonists) (ADH-RAS), Medication Adherence for Diabetes Medications (ADH-Diabetes), and Statin Use in Persons with Diabetes (SUPD) measures) via the Patient Safety Analysis Web Portal for sponsors to review and download. Part D sponsors can use the Patient Safety reports to compare their performance to overall averages and monitor their progress in improving their measure rates. In the April 17, 2023, HPMS memorandum titled, *Information to Review Data Used for Medicare Part C and D Star Ratings and Display Measures,* CMS reminded sponsors of the various datasets and reports available for sponsors to review their underlying measure data that are the basis for the Part C and D Star Ratings and display measures, including the monthly Part D Patient Safety measure reports. We expect sponsors to review their monthly Patient Safety reports that include measure rates along with available underlying administrative data and alert CMS of potential errors or anomalies in the rate calculations per the measure specifications in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings.

Reviewing administrative data for the Patient Safety measures is a time-consuming process. In addition, once CMS implements SDS risk adjustment for the three Medication Adherence measures, as finalized in the April 2023 final rule (88 FR 22265 through 22270), the final measure rates, which are calculated in July after the end of the measurement period, would require increased processing time to calculate. To allow enough time for CMS to review a sponsor's administrative data and ensure the accuracy of the final calculated Patient Safety measure rates, we proposed that sponsoring organizations' requests for CMS review of administrative data must be received no later than the annual deadline set by CMS.

Beginning with the 2025 measurement year (2027 Star Ratings), we proposed at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year. We stated in the November 2023 proposed rule that, similar to the implementation of §§ 422.164(h)(1) and (2) and 423.184(h)(1) and (2), to provide flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we intend to announce the deadline in advance either through the process described for changes in and adoption of payment and risk adjustment policies section 1853(b) of the Act (that is, the annual Advance Notice and Rate Announcement) or an HPMS memorandum.

Given the timing of the publication of the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and of this proposal, we stated that we would announce the deadline for measurement year 2025 in the final rule that addresses proposed §§ 422.164(h)(3) and 432.184(h)(3). In subsequent years, we would announce annual deadlines in advance via annual Advance Notice and Rate Announcement, or by a HPMS memorandum. For the 2025 measurement year (2027 Star Ratings), we stated that we expected this deadline to be May 18, 2026. In establishing this deadline, we factored in data completeness along with operational deadlines to produce the final Star Ratings. These requests may be time-consuming to review, and it is beneficial to receive the requests before the final rates are calculated and before the first plan preview. Historically, we find that PDE data for performance measurement are complete by April of the following year (that is, PDE data for Year of Service (YOS) 2025 is generally complete by April of 2026) even though the PDE submission deadline is established at the end of June following the payment year.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal to set an annual deadline for MA organizations or Part D sponsors to request reviews of its administrative data for the Patient Safety measures. A few commenters supported the proposal but requested to move the deadline to mid-late June or have a phased-in approach to set multiple deadlines based on PDE dates of service to facilitate a complete review.

Response: We appreciate the support received for this proposal. We proposed May 18, 2026, as the initial deadline for the 2025 measurement year for the 2027 Star Ratings and announced the date in the proposed rule due to the timing of the publication of the CY 2025 Advance Notice and Rate Announcement. The deadline was selected due to the time to complete the reviews and calculate the rates, and because the PDE data used to calculate the Patient Safety measures are generally complete by that point based on our analysis. We will continue to monitor the number of sponsor requests for administrative reviews for the Patient Safety measures, the time it takes for CMS to complete the reviews, and data completeness. In future years, we intend to announce the deadline through the annual Advance Notice and Rate Announcement or an HPMS memorandum and may adjust the deadline accordingly. We note that § 422.164(h)(3) and 423.184(h)(3), as proposed and finalized, do not require CMS to announce the deadline through the Advance Notice and Rate Announcement, which permits CMS the flexibility to use other means (such as an HPMS memo) to announce the deadline by which sponsoring organizations may request CMS to review their administrative data for the Patient Safety measures.

Comment: A commenter noted they supported the proposal for plans to request that CMS review their administrative claims data used for the Part D Patient Safety measures.

Response: We proposed to establish a deadline for sponsors to request that CMS review their administrative data

used for the Star Ratings Part D Patient Safety measures because the requests are time consuming, and we need to allow sufficient time for the reviews especially after implementation of the SDS risk adjustment for the Medication Adherence measure calculations. However, CMS has always permitted sponsors to make these requests. We provide detailed Patient Safety measure reports to sponsors on a monthly basis via the Patient Safety Analysis Web Portal to monitor their performance and alert CMS if potential errors or anomalies are identified. Then, CMS provides instructions on how to securely submit data for review. We will continue to provide information through HPMS memoranda on the process and procedures to request CMS review of these administrative data.

Comment: We received some suggestions to expand the administrative reviews to include other forms of payment outside of the Medicare PDEs for Patient Safety reports such as cash payment data, Veteran Affairs benefits, or other supplemental data.

Response: The Medicare Part C & D Star Ratings Technical Notes, available on the Part C and D Performance Measure web page [184] for each year's Star Ratings, outline the data sources used to calculate the Star Ratings Part D Patient Safety measures. Per § 423.184(d)(1)(v), non-substantive updates, including updates to data sources, to the Part D measures must be announced during or in advance of the measurement period through the Advance Notice process. (The same general rule applies as well to Part C measures per § 422.164(d)(1)(v).) CMS does not accept PDEs for claims that were not submitted for processing and/or reimbursement under the plan by either a network pharmacy or enrollee as discussed in the May 11, 2012, HPMS memorandum, *Prohibition on Submitting PDEs for non-Part D Prescriptions.* The April 23, 2013, HPMS memorandum, *May 2013 Updates to the Drug Data Processing System,* provides scenarios in which sponsors are allowed to submit PDE records with $0.00 in drugs costs.

After reviewing the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposal at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year. For the 2025 measurement year (2027 Star Ratings) the deadline will be May 18, 2026. For subsequent years, we intend to announce the annual deadlines via the annual Advance Notice and Rate Announcement or by an HPMS memorandum.

G. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2))

We proposed to calculate the percentage of LIS/DE enrollees and percentage of disabled enrollees used to determine the CAI adjustment factor in the case of contract consolidations based on the combined contract enrollment from all contracts in the consolidation beginning with the 2027 Star Ratings. The methodology for the CAI is codified at §§ 422.166(f)(2) and 423.186(f)(2). The CAI adjusts for the average within-contract disparity in performance associated with the percentages of LIS/DE and disabled enrollees within that contract. Currently, the percentage of LIS/DE enrollees and percentage of disabled enrollees for the surviving contract of a consolidation that are used to determine the CAI adjustment factor are calculated using enrollment data for the month of December for the measurement period of the Star Ratings year for the surviving contract as described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B). To more accurately reflect the membership of the surviving contract after the consolidation, we proposed to determine the percentage of LIS/DE enrollees and percentage of disabled enrollees for the surviving contract by combining the enrollment data across all contracts in the consolidation.

We proposed to modify §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage of LIS/DE enrollees and the percentage of disabled enrollees for the surviving contract for the first 2 years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation. Once the enrollment data are combined across the contracts in the consolidation, all other steps described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) for determining the percentage LIS/DE enrollees and percentage disabled enrollees would remain the same, but we proposed to restructure that regulation text into new paragraphs (f)(2)(i)(B)(*2*) through (*4*). We proposed this change since §§ 422.166(b)(3) and 423.186(b)(3) do not address the calculation of enrollment for the CAI in the event of a contract consolidation; rather, they focus on the calculation of measure scores in the case of consolidations.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: A commenter supported finalizing as proposed and another commenter appreciated CMS providing clarity on the calculation of the CAI.

Response: We thank these commenters for their support.

Comment: A commenter felt there are several benefits to the proposal but also raised some concerns. The commenter asked for clarification on how data from multiple contracts are weighted or integrated. The commenter also requested transparent and accessible information about the adjustments so beneficiaries and advocacy groups can understand the changes and their implications. The commenter also raised concerns that if the adjustment favors larger entities or provides incentives for improved ratings post-consolidation, healthcare organizations might strategically consolidate to maximize their performance ratings.

Response: Data from the contracts involved in the consolidation are not weighted in the process we proposed and are finalizing at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B). Rather the percentage of LIS/DE enrollees and the percentage of disabled enrollees will be calculated for the surviving contract of the consolidation based on all enrollees across all of the contracts involved in the consolidation. For example, if Contract A is consolidating into Contract B as of January 1, 2025, the percentage of LIS/DE enrollees and the percentage of disabled enrollees used in determining the CAI adjustment factor for Contract B for the 2025 Star Ratings will be calculated across all enrollees in Contract A and Contract B.

Data and information related to the CAI are shared publicly in multiple ways. The CAI adjustment categories are shared each year on *CMS.gov* at the time the Advance Notice is released. Each year on the Part C and D Performance Data page on *CMS.gov*, CMS shares the CAI measure supplement with details related to the adjusted measure set for the CAI and data tables with the final adjustment categories for each contract for the given Star Ratings year: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

Regarding the commenter's concern about this adjustment potentially favoring larger entities and making

[184] *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

consolidations more likely, there is nothing about this approach that would favor a larger entity. Currently, measure-level scores are already combined across the surviving and consumed contracts, so we do not believe this relatively small technical change would create new incentives for contracts to consolidate. This approach will also not make consolidations more likely because this approach will more accurately reflect the membership of the surviving contract after the consolidation including members from the consumed contracts. In addition, the Star Ratings measure scores for the surviving contract of a consolidation are calculated so that the scores reflect the membership of the surviving contract after the consolidation as specified at §§ 422.162(b)(3) and 423.182(b)(3).

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revision at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage LIS/DE enrollees and the percentage disabled enrollees for the surviving contract for the first 2 years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation as proposed without modification.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

We proposed how to calculate the HEI reward in the case of contract consolidations beginning with the 2027 Star Ratings. (The 2027 Star Ratings would be the first Star Ratings to include the HEI.) The methodology for the HEI reward is codified at §§ 422.166(f)(3) and 423.186(f)(3). The HEI rewards contracts for obtaining high measure-level scores for the subset of enrollees with the specified social risk factors (SRFs). The goal of the HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs. In calculating the HEI reward for the surviving contract of a consolidation, we want to avoid masking the scores of contracts with low performance among enrollees with the specified SRFs under higher performing contracts. We also want to avoid masking contracts that serve relatively few enrollees with the specified SRFs under contracts that serve relatively many more of these enrollees.

For the first year following a consolidation, we proposed to add new paragraphs §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to assign the surviving contract of a consolidation the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward; the existing rules laid out at §§ 422.162(b)(3)(iv) and 423.182(b)(3)(iv) address how CMS handles combining measures scores for consolidations, but do not address how CMS would handle the calculation of the HEI when contracts consolidate since the HEI is not a measure. We proposed that contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) would have a reward value of zero used in calculating the enrollment-weighted mean reward. For the second year following a consolidation, we proposed at new paragraphs §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) that, when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts in the consolidation prior to calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract following the methodology described in §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii).

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal, and another commenter appreciated the additional clarity on how the HEI will be calculated across a broad range of situations.

Response: CMS thanks these commenters for their support.

Comment: A commenter asked for additional clarification and examples of how the surviving contract's HEI reward would be calculated and combined across contracts noting that it is unclear how CMS intends to combine patient-level data ''across contracts prior to calculating the HEI score.'' The commenter stated that the proposal referenced the enrollment-weighted mean, but additional clarification and examples would be helpful.

Response: The methodology for combining data across contracts in the consolidation when calculating the HEI reward for the surviving contract will depend on which year the consolidation is in. In the first year following a consolidation, the HEI reward for the surviving contract will be calculated as the enrollment-weighted mean reward of the HEI rewards for all contracts in the consolidation using July enrollment from the most recent measurement year used in calculating the HEI.

In the second year following a consolidation, patient-level data for the measurement years used in calculating the HEI will be combined across contracts in the consolidation by assigning members from the consumed contract(s) to the surviving contract. These combined patient-level data will be used to calculate the HEI score and reward for the surviving contract, including the calculation of the percentage of enrollees with the specified SRFs for the surviving contract and the surviving contract's measure scores for the subset of enrollees with the specified SRFs following the methodology at §§ 422.166(f)(3) and 423.186(f)(3).

For example, if Contract A is consolidating into Contract B as of January 1, 2027, the first year following the consolidation is 2027. Therefore, the HEI reward for the 2027 Star Ratings will be calculated for Contract A and Contract B separately using data from measurement years 2024 and 2025. The final HEI reward for Contract B (the surviving contract) will then be calculated as the enrollment-weighted mean of the HEI rewards for Contracts A and B using enrollment from July 2025. If Contract A had an HEI reward of 0.066667 and July 2025 total enrollment of 10,000 and Contract B had an HEI reward of 0.235897 and July 2025 total enrollment of 5,000, then the final HEI reward for Contract B would be 0.123077 ((0.066667 * 10,000 + 0.235897 * 5,000)/(10,000 + 5,000)).

Continuing this example when calculating the HEI reward for the 2028 Star Ratings for Contract B (that is, the surviving contract), the patient-level data from measurement years 2025 and 2026 will be combined for Contracts A and B. That is, the patient-level data from measurement years 2025 and 2026 used to calculate the HEI score and reward for Contract B will contain all enrollees from Contracts A and B.

Comment: A commenter recommended CMS specify that total enrollment, as opposed to enrollment of beneficiaries with the specified SRFs, will be used in calculating the enrollment-weighted mean of the HEI rewards.

Response: Total contract enrollment as of July of the most recent measurement year used in calculating

the HEI will be used to calculate the enrollment-weighted mean HEI reward for the surviving contract in the first year following the consolidation. Based on this, we are finalizing as proposed with an additional revision to §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to clarify that total contract enrollment is used from July of the most recent measurement year. As illustrated in the example above where Contract A is consolidating into Contract B as of January 1, 2027, we use total enrollment as of July 2025 to calculate the enrollment-weighted mean HEI reward for Contract B (the surviving contract) in the 2027 Star Ratings.

Comment: A few commenters stated that expanding eligibility for the HEI reward to more MA plans would reduce the likelihood that currently ineligible plans might pursue contract consolidations to ''game'' the system.

Response: The proposed approach to calculating the HEI reward in the case of consolidations is appropriate because the HEI reward captures the entire population of enrollees with SRFs in the surviving contract. With regard to expanding eligibility for the HEI reward, one of the goals CMS considered when developing the HEI reward was to avoid rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve few enrollees with those SRFs relative to their total enrollment, making it easier to do well. As discussed in the April 2023 final rule, 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.

Comment: A commenter stated the proposal should be closely evaluated for the impacts of private equity, specifically the impacts mergers and acquisitions with private equity involvement may have on enrollment of systemically excluded populations, beneficiaries who meet the SRF threshold requirements, and the level of integration within plans.

Response: We do not believe that there is anything in the proposal, which we are finalizing with clarifications, for how to calculate the HEI reward for consolidating contracts that would make private equity involvement more likely. Calculating the HEI reward for the surviving contract in a consolidation as proposed will ensure the HEI reward accurately reflects the membership of the surviving contract after the consolidation. In addition, the Star Ratings measure scores for the surviving contract of a consolidation are calculated so they reflect the membership of the surviving contract after the consolidation as specified at §§ 422.162(b)(3) and 423.182(b)(3).

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the addition of §§ 422.166(f)(3)(viii)(A) and (B) and 423.186(f)(3)(viii)(A) and (B) as proposed with a modification to clarify that total contract enrollment from July of the most recent measurement year is used in calculating the enrollment weights in the first year following the consolidation.

H. Quality Bonus Payment Appeal 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 an MA contract to appeal its 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 and 21491), §§ 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.

1. Administrator Review

In the November 2023 proposed rule, we proposed to revise the language at § 422.260(c)(2)(vii) to provide the CMS Administrator the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance. We proposed that if the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. Under this proposal, if the Administrator does review and modify the hearing officer's decision, a new decision would be issued as directed by the Administrator. This proposed amendment would be implemented for all QBP appeals after the effective date of the final rule.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Commenters supported providing the Administrator the opportunity to review hearing officer decisions. A few asked for clarification of the criteria that trigger a review by the Administrator, including whether plans can request this review. A commenter requested we modify this proposal such that Administrator review serves as another level of appeal opportunity for plans, and another asked that we document clear modes of communication to ensure timely receipt of information.

Response: CMS appreciates the support. The Administrator will have the discretion to review (or review and modify) all hearing officer decisions during the 10 business day period established in the regulation. This is not another appeal opportunity for MA organizations. Information about QBP appeals is communicated promptly via email.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed the revision of § 422.260(c)(2)(vii) to state that the CMS Administrator has the discretion to review and modify the hearing officer's decision on a QBP appeal within 10 business days of its issuance by the hearing officer.

2. Permissible Bases for 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. In the December 2022 proposed rule, we proposed to clarify in § 422.260(c)(3)(iii) some additional aspects of that administrative review process for appeals of QBP status determinations that are consistent with how we have historically administered the appeals process.

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 (for example, 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 proposed 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 proposed 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 (MPF) pricing files, data from the Medicare Beneficiary Database Suite of Systems, Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources. The listed data sources have 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 using data 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 NCQA. 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 per § 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 also proposed 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 such as telephone numbers and language preference information provided directly by the MA and PDP contract. There are detailed specifications for data collection [185] for vendors to follow; CMS conducts oversight of the data collection efforts of the approved survey vendors.

Measures derived from PDE data, Medicare Beneficiary Database Suite of Systems, enrollment data from the 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 System (DDPS), which processes and validates the data with extensive system edits.[186] CMS also has an outside analytic contractor independently review PDEs and work with sponsors on data integrity issues.[187] 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, 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.[188]

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. We proposed to modify § 422.260(c)(2)(v) so that the MA organization must provide a preponderance of 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 also proposed to add 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.

If the reconsideration official or 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 proposed additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down

[185] 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/*.

[186] DDPS edit list effective for CY2024 is available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/PFYJBZSUNW~Prescription%20Drug%20Program%20(Part%20D)~References*.

[187] For background on this process see April 29, 2022, memorandum to sponsors *Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2022 Benefit Year* available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Continuation_PDE_Reports_and_Analysis_Reporting_Initiatives_2022_508_0.pdf*.

[188] See May 28, 2021 HPMS memorandum, Contract Year (CY) 2022 Part D Pricing Data Submission Guidance. *https://www.cms.gov/files/document/cy2022drugpricingsubmissionguidelines05282021final.pdf*.

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 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 recalculation 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 recalculation, the new rating will be used. For example, if CMS has to do a systematic recalculation for the 2024 Star Ratings following the release of the preliminary 2025 QBP ratings, a contract's 2024 Star Ratings used for the 2025 QBP ratings will not be decreased but the change that caused a systematic recalculation will be addressed when the 2025 Star Ratings are calculated (*e.g.,* if the recalculation resulted in an update to the 2024 Star Ratings cut points for a measure, the updated cut points would be used to determine guardrails for the 2025 Star Ratings. Likewise, if the recalculation resulted in a change in measures scores, the updated measure scores would be used in calculating the improvement measures). If the recalculation of the 2024 Star Ratings results in a higher rating for a contract, the higher rating will be used. We proposed 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 solicited comments on this proposal.

Comment: A handful of commenters did not support CMS's proposal to add a provision to the QBP appeals process to clarify that certain data sources would not be eligible for requesting an administrative review. They did not support restricting the opportunity to appeal to certain measures. A commenter noted that if a sponsoring organization believes it may have been unfairly penalized in the Star Ratings calculations, the organization should have a venue to bring that argument forward, regardless of measure source. A commenter stated that the survey data collected for CAHPS and HOS measures are subjective, and the collection methods for these surveys may result in bias due to the diverse beneficiary responses and differences in survey and digital literacy across member populations. This commenter noted that plans should retain the right to raise methodological questions about the accuracy of survey measure scores given that the measures are case-mix adjusted, the potential for incorrect adjustments, and invalid responses from beneficiaries.

Response: As we noted in the proposed rule, this proposal was to clarify and codify in regulation existing subregulatory guidance on how we have historically administered the appeals process. The data sources that cannot be appealed for data inaccuracy have 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 survey data, contracts may (and under this final rule may continue to) appeal calculation errors such as incorrectly calculating the case-mix adjustments, but they cannot claim that there is a data inaccuracy in beneficiary responses or appeal beneficiary responses. CMS does not agree that CAHPS or HOS survey responses are subjective. These responses represent the viewpoint of the beneficiary but that is the goal and purpose of the surveys—to gather and reflect the beneficiary's experience with the plan. A contract cannot dispute how a beneficiary responds to a survey and the rating the beneficiary gives their plan, for example. Part C and D sponsors contract with CMS-approved survey vendors to administer the surveys, and these vendors follow detailed data administration protocols to ensure the accuracy of the data collected and that the data collection process, including the survey administration, is free from bias.

Comment: A commenter noted that PDE changes are allowed for approximately 5 years after the close of a contract year, and while it is rare to need to appeal these rates, the possibility exists. Therefore, the commenter believed that prohibiting QBP appeals on data inaccuracies in PDE data used for Star Rating measures was not appropriate.

Response: For the Part D measures that use PDE data, the 2024 Medicare Part C & D Star Ratings Technical Notes [189] state that original and adjustment final action PDEs submitted by the sponsor and accepted by the drug data processing system (DDPS) prior to the annual PDE submission deadline are used to calculate this measure and that PDE adjustments made post-reconciliation are not reflected in this measure. Therefore, changes that the Part D sponsors make to their PDE data post-reconciliation will not be considered in the Part D Star Rating calculations and any potential impact to the QBP as a result of post-reconciliation changes are not appealable.

As we stated in the proposed rule, CMS validates the PDE data submitted by the Part D sponsors. Part D sponsors submit PDE records to CMS through DDPS which performs detailed validation, reports processing outcomes, and stores PDE records. Through the PDE edit or error code process, DDPS performs checks of the PDE records for format, integrity, and validity before storing the data for future payment calculations. There are numerous checks that could trigger PDE error codes related to missing/invalid data, beneficiary eligibility, low-income eligibility, benefit phase, NDC-level validity and coverability, basic costs accounting, detailed financial field calculations, among others.[190] Error correction/resolution is a central component in ensuring the acceptance, accuracy, and completeness of a sponsor's PDE records. Sponsors should

[189] *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

[190] See the DDPS Edit download available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References.*

resolve issues that triggered PDE edits/error codes in a timely manner.[191] The data must be submitted and accepted by the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify (based on best knowledge, information, and belief) that the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement (42 CFR 423.505(k)(3)). CMS uses PDE data that were submitted prior to the PDE submission deadline for the Part D payment reconciliation and certified by the Part D sponsor in the Part D Star Ratings calculations.

We have historically not allowed sponsors to appeal Part D Star Rating measures based on incorrect PDE data because there is already an alternative process to help sponsors identify issues through the PDE error code process, as well as a process in place for sponsors to make PDE data corrections prior to the PDE submission deadline for the Part D payment reconciliation. However, there are many opportunities for sponsors to review their data to ensure accurate data are used in the Star Ratings program. CMS annually reminds sponsors of the various datasets and reports available to review their underlying measure data that are the basis for the Part C and D Star Ratings and display measures. Every April, we remind sponsors to alert CMS of potential errors or anomalies in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings. Another memorandum, sent annually in April, outlines updates to the Medicare Part D Patient Safety measures and reports. In addition, Patient Safety User Guides and monthly reports are available for Patient Safety measures through the Patient Safety Analysis Web Portal. Revising the QBP appeal process from how it is currently administered to provide additional opportunities for sponsoring organizations to retroactively challenge their PDE data would unnecessarily burden the QBP appeal process, undermine the existing PDE submission, review, and correction processes, and eliminate the incentive of plans to ensure that CMS has accurate data on which to calculate the Star Ratings.

Comment: A commenter expressed concern that ''other Federal Data Sources'' is a very broad term.

Response: As we noted in the preamble, an example of Federal data sources used in the Star Ratings is FEMA data regarding disaster declarations. Federal data sources are any systems of record or authoritative data sources held by the federal government. To the extent that any new Star Ratings measure is based on Federal data sources that are not specifically listed in § 422.260(c)(3)(iii), we encourage commenters in future rulemakings proposing such new Star Ratings measures to submit concerns about whether such Federal data sources are the appropriate authoritative data or should be subject to additional opportunities for sponsoring organizations to challenge data issues using the QBP appeal process.

Comment: A commenter supported the proposal, stating that the two plan preview periods provide sufficient opportunities to refute suspected errors.

Response: We appreciate the support.

3. Burden of Proof

We received no comments on the 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, § 422.260(c)(1)(i) clarifying that ratings can go up, stay the same, or go down based on an appeal of the QBP determination, and § 422.260(d) clarifying 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.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposed clarifications at § 422.260(c)(1)(i), (c)(2)(v), (c)(3)(iii), and (d) with a small revision to paragraph (d) to clarify that information provided during the administrative review process may include information from other MA organizations and slight reorganization to § 422.260(c)(3)(iii) to improve the clarity of the regulation. As these clarifications and revisions to the regulation are consistent with current practice and policy and do not substantively change the appeal rights of an MA organization, CMS is applying these changes immediately on the effective date of the final rule and to the 2025 Star Ratings.

VIII. Improvements to Special Needs Plans

A. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

Under section 1859(b)(6)(B) and (f)(2) of the Act, Institutional Special Needs Plans (I–SNPs) are MA special needs plans (SNPs) that 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. ''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 explicitly listed as part of the definition of ''institutionalized'' at § 422.2 but meets both of the following criteria: (i) it furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and (ii) its 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 whether 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.

[191] See HPMS memorandum, ''Revision to Previous Guidance Titled ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,'' '' October 6, 2011.

CMS currently permits MA organizations to submit SNP applications that are restricted to institutionalized individuals only or institutionalized-equivalent individuals only, or to submit an application for a combination I–SNP that covers beneficiaries who qualify for either institutionalized or institutionalized-equivalent status but are enrolled under the same plan.

We proposed 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's current MA application process. In addition, we proposed 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 explained that adding these four definitions would clarify the specific standards that are applicable to I–SNPs, as distinguished from other MA plans and from other MA SNPs. The proposed revisions to the definitions include tying the definitions of ''institutionalized'' and ''institutionalized-equivalent'' in § 422.2 and the list of eligible institutions set forth in that definition to the proposed definition of I–SNP. In addition, our proposed definitions of the terms ''facility-based institutional special needs plan (FI–SNP)'' and ''hybrid institutional special needs plan (HI–SNP)'' included specific performance requirements tied to the type of special needs individual enrolled in the plan, while the proposed definition of ''institutional-equivalent special needs plan (IE–SNP)'' focused on how IE–SNPs restrict enrollment to MA-eligible individuals who meet the definition of ''institutionalized-equivalent.'' Specifically, we proposed that the definition of the term facility-based institutional special needs plan (FI–SNP) would include that such plans own or contract with at least one institution in each county in the plan's service area and with each institution that serves enrollees in the plan. This approach of specifying certain requirements as part of the definition of a specific type of plan is consistent with how CMS has adopted regulatory definitions for D–SNPs, FIDE SNPs, and HIDE SNPs in § 422.2. The proposed definitions clarified that MA organizations may offer I–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 codifies our current sub-regulatory guidance and those practices CMS has historically used during the MA application process and would not change current or future eligibility and enrollment requirements for I–SNP plan subtypes. In addition, adopting regulatory definitions that are specific to the type of I–SNP and the populations served by the I–SNPs allows clearer distinctions and rules about regulatory requirements that are applicable to a specific type of I–SNP. For example, we proposed in the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (the ''November 2023 proposed rule'') [192] to amend § 422.116 to adopt an exception to existing network adequacy requirements for facility-based I–SNPs, which are special needs plans that restrict enrollment to individuals who meet the definition of institutionalized, own or contract with at least one institution, and own or have a contractual arrangement with each institutional facility serving enrollees in the plan. See section VIII.B of the November 2023 proposed rule and section VIII.E of this final rule for more information about that proposal.

Lastly, we proposed 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'' at § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized. The proposed new § 422.101(f)(2)(vi) would codify longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the Medicare Managed Care Manual (MMCM) that is designed to provide I–SNP enrollees protections regarding access to care coordination and communication between providers and I–SNP staff. Under our proposal, access would be assured for I–SNP enrollees to care coordination services from I–SNP clinical and care coordination staff that are employed by the MA organization offering the I–SNP or under contract with the I–SNP to furnish healthcare, clinical or care coordination services. As we noted in the December 2022 proposed rule, I–SNP clinical and care coordination staff may be employed by the MA organization offering the I–SNP or be 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 I–SNP staff. In the proposed rule, we explained 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 would include provisions allowing access for ISNP staff would better protect beneficiaries.

We received the following comments on our proposals, and our responses follow:

Comment: A commenter sought clarification regarding the contracting requirements for Hybrid Institutional SNPs (HI–SNPs); specifically, the commenter asked that CMS clarify the requirement that HI–SNPs ''must own or have a contractual arrangement with each institutionalized facility serving enrollees.'' The commenter stated that it may not be possible to have a contract with a nursing home in a rural area, or the existing single facility may be of low quality, but enrollees in that facility would be well-served by having access to providers located in adjacent counties for service, and still benefit from the additional support and coordination offered by the I–SNP.

Response: We appreciate the commenter's concerns related to service area requirements and access for their enrollees who might be able to seek services in counties adjacent to the HI–SNP's service area. In setting the proposed requirements for HI–SNPs, CMS considered that the plan would be a hybrid and thus include both MA-eligible individuals who meet the definition of ''institutionalized'' and MA-eligible individuals who meet the definition of ''institutionalized-equivalent.'' Because HI–SNPs may enroll individuals that meet the definition of ''institutionalized'' under § 422.2, the performance requirements for FI–SNPs that exclusively serve institutionalized individuals must also apply to the HI–SNP in order to ensure that the institutionalized enrollees of the HI–SNP are similarly protected and receive the necessary services. We proposed that FI–SNPs must own or have a contractual arrangement with

[192] The November 2023 proposed rule can be found here: *https://www.federalregister.gov/d/2023-24118.*

each institutionalized facility serving enrollees in the plan to align with longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the MMCM. Under Chapter 16B, CMS has interpreted contractual arrangement to mean a network participation contract and will continue to do so in this final rule. This policy provides an important beneficiary protection as it ensures that the MA organization that offers the FI–SNP or HI–SNP contracts with the institution in order to ensure that the institution adheres to critical care management measures and MOC standards that apply to the I–SNP. Therefore, HI–SNPs that also enroll and cover institutionalized special needs individuals must own or contract with at least one institution, specified in the definition of ''institutionalized'' in § 422.2, for each county within the plan's service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan in order to comply with the requirements set forth at § 422.2 for the purposes of defining a special needs individual. For example: if a Medicare beneficiary seeks to enroll in a HI–SNP, the plan must own or have a contract with the long-term care facility where the beneficiary resides—otherwise, the beneficiary is not eligible for enrollment. This requirement is consistent with sub-regulatory guidance in section 20.3.4 the Chapter 16B of the MMCM.

In CMS's experience, I–SNPs have been able to successfully comply with this requirement to own or contract with the necessary institutions. CMS will continue to monitor compliance with this requirement in reviewing applications for I–SNPs and in monitoring and overseeing the MA program. In addition, we are adopting a slight clarification to the definition of FI–SNP, which will also apply to HI–SNPs, to use the phrase ''in the plan's service area'' Instead of the proposed phrase ''within the plan's county-based service area.'' This revision better aligns with the definition of Service Area in 42 CFR 422.2 ''Service area.'' This revision does not change the substance of the requirement that each FI–SNP and HI–SNP own or have a contract with at least one institution in each county of the plan's service area.

Comment: A commenter expressed concern that I–SNPs do little to assist enrollees who wish to return to a community setting because of incentives to maintain plan enrollment, and that most I–SNP enrollees would be better served in a D–SNP or in Traditional Medicare. While the commenter did not specify, based on the context of the comment, CMS interprets that the commenter was referring to all I–SNPs that enroll beneficiaries who are institutionalized. The commenter further stated that alternative coverage (that is, D–SNPs or Traditional Medicare) avoids the strong incentives that plague facility-based I–SNPs to keep enrollees in settings that are inappropriate for their health needs and/or does not meet their wishes. The commenter stated that more regulation of I–SNPs is required to ensure that enrollee needs are met. Another commenter expressed concerns with the increased enrollment in I–SNPs, and evidence identified in a report by MedPAC in 2013 [193] that I–SNPs are prescribing inappropriate medications, specifically, the commenter's interpretation that the report found that I–SNPs have higher rates than regular MA plans for the use of potentially harmful drugs among the elderly as well as reporting the use of drug combinations with potentially harmful interactions; and that I–SNPs could be denying beneficiaries needed hospital care, or that plan ownership of a SNF could result in denials of coverage of needed, but expensive care.

Response: We thank the commenters and share the concerns that an enrollee's residency wishes be met, and that appropriate care be provided to I–SNP enrollees by the I–SNP. In implementing a SNP model of care, the MA organization must conduct a comprehensive initial, and then annual, health risk assessment of the individual's physical, psychosocial, and functional needs as required by § 422.101(f)(1)(i). Per 42 CFR 422.101(f)(1)(ii), the MA organizations offering a SNP must also develop and implement a comprehensive individualized care plan (ICP) through an interdisciplinary care team in consultation with the enrolled beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided. The requirement at § 422.101(f)(1)(ii) for consultation with the enrolled beneficiary means that the enrollee's goals and wishes, with regards to living in the community, as well as access to covered services or treatment plans, must be captured in their ICP.

As far as evaluating whether an institutionalized individual is better served by a D–SNP, I–SNP, or Traditional Medicare, Medicare beneficiaries are free to make their own enrollment decisions regarding how to receive Medicare benefits; section 1851 of the Act provides that each MA-eligible beneficiary is entitled to elect to receive Part A and B benefits through the Traditional Medicare program or enrollment in an MA plan for which the individual is eligible. We encourage all beneficiaries to review their coverage options whether it be Traditional Medicare or Medicare Advantage and believe that the educational tools and materials we make available on *Medicare.gov* help to facilitate that decision-making. Beneficiaries may also find helpful information through the ''Medicare & You'' handbook, by calling 1–800–MEDICARE, or by contacting the State Health Assistance Program (SHIP) in their state.[194] Healthcare providers, including the long-term care institutions in which institutionalized special needs individuals reside, must respect the choice that beneficiaries make in electing their Medicare coverage whether it is through Traditional Medicare or an MA plan.[195]

We also share the commenter's concern that beneficiaries may be prescribed inappropriate medications. We note that MedPAC acknowledges in their report that this particular finding may be a result of monitoring practices among I–SNPs. MedPAC noted in 2013 that ''[a]lthough I–SNPs also have higher rates than regular MA plans for the use of potentially harmful drugs among the elderly and the use of drug combinations with potentially harmful interactions, their higher rates of monitoring of persistently used drugs suggest that drugs with potential interactions or adverse effects are also being closely monitored.'' [196] As the report notes, MedPAC suggests that I–SNPs do enroll a population with a higher use of potentially harmful drugs when compared to non-I–SNPs, but then suggests that I–SNPs are closely monitoring for potential adverse events. CMS publishes SNP data pertaining to the Star Ratings quality measure Care for Older Adults—Medication Review,

[193] The commenter cites MedPAC, Chapter 14 (March 2013); 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.*

[194] Beneficiaries can find their local SHIP through *https://www.shiphelp.org/,* and clicking on ''Find Local Medicare Help.''

[195] CMS previously addressed this matter in the memo ''Memo to Long Term Care Facilities on Medicare Health Plan Enrollment (October 2021), see *https://www.cms.gov/files/document/ltcfdisenrollmentmemo.pdf.*

[196] See MedPAC, Report to the Congress: Medicare Payment Policy, March 2013, ''Medicare Advantage special needs plans.'' *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.*

which MA special needs plans are required to submit as part of the Healthcare Effectiveness Data and Information Set (HEDIS) reporting requirements, and Use of High-Risk Medications in Older Adults (a HEDIS measure), as part of Final Medicare Special Needs Plans HEDIS® Performance Results annual reports, and will continue to review this performance data for all I–SNPs.[197]

Comment: A commenter expressed support of the HI–SNP model and stated that restricting enrollment in HI–SNPs to include both MA-eligible individuals who meet the definition of ''institutionalized'' and MA-eligible individuals who meet the definition of ''institutionalized-equivalent'' will ensure individuals in both categories receive necessary supports across the continuum of their care needs without having to experience the disruption of changing Medicare coverage types should an enrollee need for more extensive long-term care. They also believe the HI–SNP and IE–SNP models create an incentive for an I–SNP to serve people who can safely live in the community and could significantly improve continuity and coordination of care for individuals residing in states that do not offer integrated duals programs.

Another commenter expressed support for the proposed clarification of I–SNP types and requested that CMS report enrollment in the different types of I–SNP in the CMS MA monthly publicly available enrollment reports to better understand the growth in these plans.

Response: We thank the commenters for their support of our proposal. We note that CMS currently publishes monthly SNP enrollment data on the CMS website.[198] These monthly reports provide I–SNP enrollment totals as well as the number of active I–SNP plans. CMS may explore the possibility of providing enrollment and plan data at the SNP subtype level in the future.

Comment: A commenter noted that CMS requested comment on whether the proposed regulatory text needs to more specifically address information-sharing or other issues related to I–SNPs being able to access information about and gain access to facilities where their enrollees reside. The commenter cited a statement in the December 2022 proposed rule related to the I–SNP proposal that CMS has received reports that providers sometimes fail to share relevant information regarding an enrollee's health or need for care with the I–SNP staff. The commenter recommended that, prior to revising the MA regulations, CMS should review the issue for substance and specifics, including looking at best practices related to joint facility staff and plan staff participation in care management, which could provide CMS with some useful examples or evidence suggesting that facilities requiring plan reliance on paper documentation over in person or virtual participation in facility activities is a sub-optimal alternative.

Response: We thank the commenter for supporting our proposal 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. As proposed and finalized here, § 422.101(f)(2)(vi) reflects longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the MMCM that is designed to provide I–SNPs enrollees with protections regarding access to care coordination and to ensure communication between providers and I–SNP staff. We expect MA organizations sponsoring I–SNPs to have communication provisions in their contracts with network long-term care providers where enrollees reside that should stem barriers to information sharing. While our experience with this long-standing sub-regulatory guidance has given us insight into the need for this policy as set forth in our proposed rule, we welcome continued input on this topic should additional guidance or rulemaking be needed in this area.

Comment: Another commenter noted codifying CMS's sub-regulatory guidance for I–SNPs is appropriate as I–SNPs continue to grow in enrollment. The commenter further elaborated by noting that is essential that the facility share data with the I–SNP such as data regarding the clinical, psychosocial, health-related social needs of their I–SNP enrolled residents, as well as other data relevant to the plan of care is essential to achieving the best possible outcomes for enrollees living in an institutional setting. The commenter noted that CMS's expectations and requirements for MA plans should align across health plan types and be consistent with the health information-sharing requirements of the Medicare and Medicaid programs.

Response: We thank the commenter for their support of the proposed rule and agree that data-sharing among plans, facilities and providers is crucial to supporting the health care needs of I–SNP enrollees. We note, however, that as proposed and finalized, § 422.101(f)(2)(iv) imposes obligations on I–SNPs, and policy modifications regarding data-sharing more broadly, such as between non-SNP MA plans and providers or facilities, is outside the scope of this rule.

Comment: A commenter noted that CMS should apply the level of care requirements in the definition of ''institutionalized-equivalent'' under § 422.2, which would be applied to the proposed definitions of IE–SNP and HI–SNPs, to improve the Part D program, that is, that CMS should require Part D plans to engage in a similar assessment of whether enrollees that are living in the community require an institutional level of care. The commenter further noted that enrollees in IE–SNPs/HI–SNPs and Part D programs have substantially similar chronic conditions and cognitive impairments, including the prevalence of these conditions, the dual eligibility of enrollees, and prescription drug needs of Medicare enrollees. The commenter suggested that if CMS amended various aspects of Part D regulations to address the subset of enrollees with such needs, it would significantly improve the care and services enrollees receive through the Part D program as well as the Medicare and Medicaid programs overall. For example, the commenter noted that if CMS were to increase LTC pharmacy services regardless of setting, medication management would be more effective, patient outcomes would improve, and overall health care spending would be lower. The commenter noted that CMS should consider tools and processes to allow Part D plans to identify enrollees' institutional level of care needs and incorporate that into the information Part D plans must obtain regarding Part D enrollees.

Response: We appreciate the commenter's suggestion regarding the use of a tool to assess the level of care (LOC) needs of enrollees in the Part D program. We note that the use of these tools for determining that the individual requires an institutional LOC is codified at 42 CFR 422.2 ''institutionalized-equivalent,'' for purposes of I–SNP eligibility and enrollment. We proposed

[197] The Care for Older Adults—Medication Review measure is used in the Medicare Advantage and Part D Quality Star Ratings that are available online at *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.* In addition, multi-year reports covering a selection of HEDIS measures reported by MA SNPs can be found here: *https://www.cms.gov/medicare/enrollment-renewal/special-needs-plans/data-information-set.*

[198] A PDF and Excel version of each monthly report can be found here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.*

and are finalizing clarifications of the specific standards that are applicable to I–SNPs, as distinguished from other MA plans and from other MA SNPs, as well as codify FI–SNP and IE–SNP enrollee protections regarding access to care coordination and communication between providers and I–SNP staff. CMS is implementing this proposal by adding 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's current MA application process, and only addresses requirements that I–SNPs must implement for their enrollees. We did not propose changes to Part D requirements of the nature suggested by the commenter. Thus, the comment to apply I–SNP requirements more broadly to Part D plans is out of scope for this rule.

All MA SNPs must cover the Medicare Part D benefit per the definition of specialized MA plans for special needs individuals in § 422.2; therefore, the individual care plan for all I–SNP enrollees should address Part D benefits as well as MA basic benefits (that is, Part A and B benefits) and MA supplemental benefits.

After considering all the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing definitions of the terms Facility-based Institutional special needs plan (FI–SNP), Hybrid Institutional special needs plan (HI–SNP), Institutional special needs plan (I–SNP), and Institutional-equivalent special needs plan (IE–SNP) at § 422.2 largely as proposed. In the definitions of FI–SNP, HI–SNP, and I–SNP, we are slightly reorganizing the definitions to improve their readability. We are modifying the definition of FI–SNP to more clearly provide how FI–SNPs must own or contract with institutions as described in the definition. Finally, we are also revising the definition of FI–SNP by replacing ''with the plan's county-based service area'' with ''in the plan's service area.'' This revision better aligns with the definition of Service Area in 42 CFR 422.2 ''Service area.''

In addition, after considering all the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to § 422.101(f) to add a new paragraph (f)(2)(vi) as proposed to require the model of care for each I–SNP (regardless of the type of I–SNP) to 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.

B. 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)(2) through (4) of the Act, SNPs are required 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. Section 1859(f)(5)(A) of the Act, added by Section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110–275), imposes specific care management requirements for all SNPs effective January 1, 2010. 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).

In the December 2022 proposed rule, we proposed to codify certain sub-regulatory 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.

We provide additional summaries of the proposed MOC provisions and responses to comments received below.

1. Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs) (§ 422.101(f)(3)(iii))

Section 1859(f)(7) of the Act requires 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 CMS 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 (CMS–4190–F2) (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 certain 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, as required under part 422, subpart K, to demonstrate that they meet SNP specific requirements, including the requirements in § 422.101(f) that MA organizations offering a SNP implement an evidence-based MOC to be evaluated by the NCQA; in § 422.107 that D–SNPs have a contract with the State Medicaid agencies in the states in which they operate; and 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. 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, issued, and updated guidance on the MOC to improve plan performance and beneficiary care. Section 1859(f)(5) of the Act outlines 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. These provisions in section 1859(f)(5) of the Act are the statutory foundation for much of our subsequent regulatory standards for the MOC. 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). 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. Additional background on our existing guidance and the importance of the MOC is in the proposed rule at 87 FR 79572 through 79573.

In the December 2022 proposed rule, we proposed to codify the SNP MOC scoring protocols by amending § 422.101(f)(3)(iii) to include the current sub-regulatory 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 proposed 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 proposed 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. A full list of the most recent elements and factors used in evaluating and scoring the MOCs is in the Model of Care Scoring Guidelines for Contract Year 2025; 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.'' [199] 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 proposed 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 proposed 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 proposed 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 also proposed, at new paragraph (f)(3)(iii)(B), to codify different the approval time limits for the MOCs of I–SNPs and D–SNPs, basing the approval period on the final score of the MOC on the aggregate minimum benchmark. We proposed 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 proposed 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 any 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 also proposed that the opportunity to cure deficiencies in the MOC is only available once per scoring cycle for each MOC submission. We noted that 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 for a contract year. 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

[199] The Model of Care Scoring Guidelines for Contract Year 2025 can be found here: *https://snpmoc.ncqa.org/static/media/CY2025SNP_MOC_Scrng_Gdlns_508.4c71d8c17b37b33ff079.pdf.* The ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Model of Care Changes'' can be found here: *https://omb.report/icr/202105-0938-005/doc/original/111555400.pdf.*

failure to meet a necessary qualification for SNPs.

We received the following comments regarding the aforementioned provisions and provide our responses later in this section.

Comment: We received several comments addressing the SNP Model of Care Element Matrix (the Matrix),[200] which reflects the content and evaluative criteria of the MOC. One commenter suggested that CMS reduce duplication and the level of detail within the Matrix, particularly redundancies across factors, elements, and/or where there is evidence that the element or factor is not required to be part of a robust care management program.

Response: We did not propose to codify the content and evaluation criteria for approval of the MOC, and as such, we do not believe these comments regarding the level of specificity in the Matrix are within scope of the proposed rule. However, we will take these comments into consideration when renewing the next MOC Paperwork Reduction Act (PRA) package and for future rulemaking. CMS currently publishes the Matrix for comment 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). We encourage all parties to submit comments during the next PRA package renewal regarding MOC burden estimates.

Comment: A commenter suggested that CMS reevaluate the MOC submission process and NCQA's review of initial and renewal MOCs and to coordinate with CMS audit processes for efficiency, consistency, and effectiveness to the extent that the burden placed on SNPs to submit MOCs is commensurate with current CMS burden estimates.

Response: While we believe our current burden estimates fairly capture the MOC process, CMS will take comments suggesting a more effective MOC review process and audit system under advisement. In regard to consistency, NCQA and CMS work collaboratively to ensure MOCs are reviewed in the manner appropriate to and in alignment with the MOC submission requirements and CMS audit protocols.

Comment: A commenter recommended that CMS consider the potential impact of environmental disasters or other major shifts, such as the COVID–19 pandemic, on the implementation of the MOC's approved care management processes and policies. This commenter recommended CMS provide for the ability of plans to diverge from regular processes and activities contained in the MOC during such an event or shift.

Response: We appreciate this comment and recognize the value of such a discussion. NCQA is required by § 422.101(f)(3)(ii) to evaluate whether goals from the previous MOC were fulfilled when reviewing a new or subsequent MOC for approval. To the extent that the commenter was addressing review of an MA organization's overall implementation of its MOC, that is outside of the scope of the proposal to codify the minimum scoring benchmarks, the length of the approval period, and the availability of a cure period when a MOC fails to meet the minimum benchmarks. Actual implementation of the MOC is reviewed as part of CMS's auditing and oversight. We note that CMS does have a framework in place to convey any temporary changes needed to the MOC process or requirements through the issuance of departmental or agency communications that may be necessary during a public health emergency or similar situation, as evidenced by policy updates provided during the coronavirus disease 2019 (COVID–19) public health emergency (see CMS memo ''Information Related to Coronavirus Disease 2019—COVID–19'').[201] As we noted in that memo at the time, CMS recognized that in light of the COVID–19 outbreak, an MAO with one or more SNPs may need to implement strategies that do not fully comply with their approved SNP MOC in order to provide care to enrollees while ensuring that enrollees and health care providers are also protected from the spread of COVID–19. CMS stated then that we would consider the special circumstances presented by the COVID–19 outbreak when conducting MOC monitoring or oversight activities. For instance, CMS could permit SNPs to use real-time, audio-visual, interactive virtual means of communication to meet the face-to-face encounter requirements in an emergency if the SNP's MOC states that care coordination visits and encounters are in person. We continue to believe that this is an appropriate way to address MOC implementation during a public health emergency or similar situation. In addition, we remind MA organizations of the existing requirements at § 422.100(m) that apply during a disaster or emergency; those also apply to MA SNPs. We also reiterate, however, that even during an emergency or disaster, all enrollees, including SNP enrollees, must receive all medically necessary items and services, including care coordination.

Comment: A commenter recommended that CMS require each D–SNP to make its model of care publicly available. This commenter suggested that this would help beneficiaries and other stakeholders determine whether a given D–SNP is fulfilling obligations outlined in its own model of care.

Response: We did not propose and are not finalizing at this time a requirement for D–SNPs to publish their MOCs. All SNPs (including D–SNPs) must identify and clearly define measurable goals and health outcomes for the MOC as part of their MOC submission under MOC 4 Element B. This includes but is not limited to: identifying and clearly defining the SNP's measurable goals and health outcomes; describing how identified measurable goals and health outcomes are communicated throughout the SNP organization; and evaluating whether goals were fulfilled from the previous MOC. NCQA reviews the information provided by the SNP and will assign a failing score if the plan cannot meet all factors within the element. SNPs are also required to submit documentation showing plan compliance to their approved MOC as part of the current CMS SNP audit process. Following NCQA's review, each SNP is assigned a score and an associated approval period. These MOC scores are available on NCQA's website, cover the past three years of submissions, and include NCQA's detailed scoring of each MOC Element. We encourage interested parties to review the materials and information posted by NCQA. CMS will continue to employ a robust audit protocol to ensure that all SNPs are implementing their MOCs appropriately.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed amendments to § 422.101(f)(3)(iii) substantially as proposed but with minor grammatical and organizational changes. As finalized, § 422.101(f)(3)(iii) establishes the aggregate minimum benchmark score for a MOC to be approved, the time period of approval, and the opportunity for an MA organization to submit a corrected MOC for re-evaluation if the MOC is scored below

[200] The MOC Element Matrix cand be found on *CMS.gov* at: *https://www.cms.gov/files/document/cy2023attachmentamodelofcarematrixinitialandrenewalsubmissionmnfnl.docx.*

[201] The memo can be found here: *https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf.*

the minimum benchmarks on NCQA's first review.

4. Amending SNP MOCs After NCQA Approval (§ 422.101(f)(3)(iv))

CMS also proposed to codify current policies and procedures for an MA organization 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 in the midst of its approved MOC timeframe. CMS announced a process for SNPs to submit MOC changes for review in the CY 2016 Final Call Letter. Currently, a DSNP 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. These kinds of 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 for review and approval. However, beginning with CY 2020, C–SNPs were required to submit MOCs annually, and thus, their MOCs receive approvals for a period of one-year. As a result of 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 substantive that notification to CMS and review of the changes to the MOC by NCQA and CMS 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. The proposed adoption of § 422.101(f)(3)(iv) was 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. We explained in the proposed rule that for this 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. In such cases, 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. As part of the December 2022 proposed rule, we proposed to establish when an MA organization may submit updates and corrections to its approved MOC.

First, we proposed to codify the off-cycle process at § 422.101(f)(3)(iv). We proposed 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 which are prohibited from submitting off-cycle submissions. 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, to guarantee the safety of enrollees, or to meet State Medicaid requirements. Although we did not propose to codify this specific language in the December 2022 proposed rule nor are we finalizing it here, CMS will continue to use this discretion when reviewing applicable submission requests. We proposed to maintain this process and codify it at § 422.101(f)(3)(iv)(A). We proposed 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 requires an off-cycle submission to ensure compliance with applicable law.

We stated in the proposed rule that we were proposing to use 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. We also stated that we were proposing, in an effort to ensure consistent application of this standard and demonstrate our intent, that these be limited situations where a revision is truly necessary, the finalized regulation text would provide that CMS would make this determination and provide directions to the MA organization. We also stated in the proposed rule that if an MA organization believed that this standard for when revision is necessary to ensure compliance by the SNP and its MOC is met, the MA organization should contact CMS for guidance and approval to submit a revision. However, the proposed regulation text did not include this standard and proposed paragraph (f)(iv)(A) stated that 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. We read the phrase ''to ensure compliance with applicable law'' to encompass the situations described in the preamble of the proposed rule (and here in the final rule) or similar situations where CMS has determined that a potential or existing violation needs to be addressed. ''Applicable law'' encompasses MA regulations and statutes, and for D–SNPs, certain Medicaid regulations and statutes; where a MOC would potentially result in harm to enrollees or changes to a MOC are necessary to ensure the safety of enrollees, we view these changes as changes required by applicable law, because the fundamental nature and purpose of the MOC is to ensure that the SNP addresses the needs of the special needs individuals enrolled in the SNP. We also stated in the proposed rule that if an MA organization believed that this standard for when revision is necessary to ensure compliance by the SNP and its

MOC is met, the MA organization should contact CMS for guidance and approval to submit a revision.

Since the beginning of the off-cycle submission process, CMS has provided guidance clarifying which MOC changes require submission to CMS and how SNPs should submit their MOC changes to CMS. We have previously said 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. However, given the level of questions we have received over the years regarding what constitutes a significant change, we proposed 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) provided 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 personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel);
- Changes to quality metrics used to measure performance.

The proposed regulation text did not include 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 to the MOC that are permitted but that do not need to be submitted through HPMS include but are not limited to:

- 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.

We also proposed, § 422.101(f)(3)(iv)(D), that SNPs may not implement any changes to a MOC until NCQA has approved the changes. We explained in the proposed rule that 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, but that the revised MOCs would not be rescored. We proposed 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 original approval period (that is, 1-year or multi-year) by NCQA. Therefore, changes made to MOC cannot be used to improve a low score. We stated how we anticipate that the current procedures and documentation processes used to implement the requirements would continue under our proposal and explained our position that such procedures and operational practices do not require rulemaking and that 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 stated that we intended 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 and that we would 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.

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. We did not include NCQA's off-cycle scoring policy and the implications in the proposed regulation text, but we are clarifying in this final rule at § 422.101(f)(3)(iv)(D) to note that all changes, as applicable under § 422.101(f)(3)(iv)(B), that are part of a SNP's off-cycle submission are reviewed by NCQA as ''Acceptable'' or ''Non-acceptable.'' By ''Acceptable,'' we mean that the changes have been approved by NCQA and the MOC has been updated; whereas by ''Non-acceptable'' we mean that the changes have been rejected by NCQA and the MOC has not been changed.

We proposed under § 422.101(f)(3)(iv)(F) to codify existing operational practices with respect to off-cycle submissions by C–SNPs. As previously discussed, currently, C–SNPs are prohibited from submitting off-cycle MOC submissions. We proposed 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. Otherwise, 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)(iv)(G) to confirm that the revised MOC is consistent with the standards outlined in the original MOC. We proposed, at § 422.101(f)(3)(iv)(G), to permit a single opportunity for a SNP to revise its off-cycle submission to revise a MOC if there is a deficiency in the submission. The cure process proposed, which is the current operational process use by NCQA, would permit 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 proposed 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 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 as the MOC has yet to go into effect. Under the proposal, we stated that we would 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, and then the start of the off-cycle submission window on June 1, 2023. In order to clarify this process, we proposed to codify this guidance at § 422.101(f)(3)(iv)(C). We proposed 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 reiterated in the proposed rule that we still believe that to substantively revise an MOC should be a rare occurrence rather than an eventuality. These proposed processes and procedures were intended to 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 sought comment on the codification of the current off-cycle MOC submission process.

We reiterated in the proposed rule that the proposed regulations reflect and would codify current policy and procedures. While we proposed that the regulations would be applicable beginning with a future year, we stated our intent to continue our current policy as reflected in the proposed rule. We also stated in the December 2022 proposed rule that the proposed changes carried no burden because the proposal was a codification of previously issued sub-regulatory guidance in Chapter 5 and other CMS transmittals to impacted MA organizations. We also explained that the proposed provisions are 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. This position continues and we believe that this final rule, which finalizes § 422.101(f)(3)(iv) generally as proposed (with several modifications to clarify the regulation) is consistent with current procedures and the approved PRA package.

We received comments to these proposed provisions regarding off-cycle revisions to approved MOCs and our responses follow.

Comment: A commenter suggested that the need for off-cycle submissions will become more frequent as the increasing number of requirements, industry developments, and ever-evolving best practices around health equity, care coordination, provider networks, and other emerging standards make it more likely that substantive changes will need to be made. Thus, the commenter reasoned, SNPs are likely to find it necessary to more frequently submit an off-cycle review so that their MOCs remain current to structures, processes, practices, and programs that are operationalized for SNP members. The commenter suggested that CMS revise and/or clarify the language on what is considered a ''substantive change'' as it remains unclear, and plans will default to assuming they should submit their MOCs. The commenter also suggested that CMS allow for some flexibility in CMS audits around MOC compliance, suggesting that when the plan documents the deviations (including the purpose and extent of any deviation) from the written/approved MOC when needed, and the plan believes the deviations are ''not-substantive'' consistent with CMS criteria, the plan should not be penalized for its failure to submit their MOC for an off-cycle review.

Response: CMS recognizes that industry developments and changes in applicable federal health care laws may impact the nature of health care delivery and care coordination among SNPs and their members. We proposed and are finalizing at § 422.101(f)(3)(iv)(A) and (B) the standards that are to be used to identify when an off-cycle submission to revise an approved MOC will be permitted.

As proposed in new paragraphs (f)(3)(iv)(A) and (B), an MA organization that offers a D–SNP or I–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:

- 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.
- D–SNPs and I–SNPs are required to submit updates or corrections as part of an off-cycle submissions based on:
  - 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;
  - Target population changes that warrant modifications to care management approaches;
  - 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;
  - 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
  - Changes to quality metrics used to measure performance.

We are making minor changes to proposed paragraphs (f)(3)(iv)(A) and (B) to increase the clarity of the regulation. We are finalizing paragraph (f)(3)(iv)(A) to provide that C–SNPs, D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law. Finalizing new § 422.101(f)(3)(iv)(A) with these revisions makes it clear that when CMS requires an off-cycle submission, such as when CMS identifies an issue during an audit, the MA organization offering the C–SNP, D–SNP or I–SNP must submit off-cycle revision to NCQA for review and approval of the necessary changes to the MOC.

We are finalizing paragraph (f)(3)(iv)(B) to specify when D–SNPs and I–SNPs are permitted to use an off-cycle submission to submit updates and corrections to their MOCs to NCQA for review and approval. As we proposed, updates and revisions or corrections of this type are permitted only for certain reasons. As finalized, § 422.101(f)(3)(iv)(B) provides that D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year if the I–SNP or D–SNP wishes to make any of the listed revisions. The list of revisions, at paragraphs (f)(3)(iv)(B)(*1*) through (*5*)

tracks the permitted changes we proposed to codify in paragraphs (f)(3)(iv)(B)(*1*) through (*5*). (87 FR 79713) We believe that the revisions we are finalizing in the regulation text are not substantive changes in policy compared to what CMS proposed in the December 2022 proposed rule but are a reorganization to clarify when requests to change the MOC are submitted. The final rule clarifies that the period between June 1st through November 30th of each calendar year is the time period for a D–SNP or I–SNP that seeks to make changes to its MOC off-cycle, to submit their updates and/or changes to the previously approved MOC. However, when CMS directs a C–SNP, D–SNP or I–SNP to make changes to their MOC in order to comply with applicable law, it is CMS who will direct the timing of the submission (and the June to November time period mentioned above might not necessarily apply). The changes described in paragraphs (f)(3)(iv)(B)(*1*) through (*5*) are generally voluntary changes that the D–SNP or I–SNP is making to its SNP operations and administration that subsequently require changes to the MOC. In these instances, D–SNP or I–SNP must seek an off-cycle revision to its MOC to implement the changes. In these cases, the changes in operation and administration are independent from any CMS direction to ensure compliance with applicable law.

A D–SNP or I–SNP that decides to make significant revisions to their existing approved MOC must 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, before implementing and using the changes to the MOC. As discussed in the preamble to the proposed rule, significant revisions within the scope of § 422.101(f)(3)(iv)(B) are those that have a significant impact on care management approaches, enrollee benefits, and/or SNP operations. The intent of the rule under § 422.101(f)(3)(iv)(B) is to codify and clearly delineate events that would be considered by CMS as significant revisions. We believe that this language is sufficient to direct plans; however, CMS will monitor the initial off-cycle period to review whether SNPs continue to submit changes that fail to meet the intent of the requirement and will provide additional examples of what is considered a significant revision within the scope of this rule, as necessary.

The proposed rule (87 FR 79575) provided examples of the type of non-significant changes that an MA organization may make *without* using the off-cycle submission and approval process. Those changes as outlined in the proposed rule included, but were not limited to, revisions to the MOC to address a change in ownership of the MA organization, changes in administrative staff and changes to demographic data. When an MA organization that sponsors a SNP has a change that is not an immaterial change as noted here and the MA organization is unsure if the change is sufficiently similar in type and scope to the changes as noted above, the MA organization should seek guidance from CMS. The list of changes that do require an off-cycle submission of updates and corrections to the approved MOC in § 422.101(f)(3)(iv)(B) is sufficiently detailed to be applied by MA organizations and CMS in the future. It is not acceptable, and it is inconsistent with this final rule (specifically § 422.101(f)(3)(iv)(D)) for an MA organization to make a change within the scope of § 422.101(f)(3)(iv)(B) without review and approval from NCQA. We recommend that an MA organization that is unsure if a change it is contemplating to its approved MOC needs to be submitted for review and approval, the MA organization should contact CMS for guidance. In such cases, CMS will apply the regulation as finalized and instruct the MA organization whether the change is within the scope of § 422.101(f)(3)(iv) as finalized.

Lastly, although some comments expressed concern about alignment of audit standards with off-cycle review and approval of MOCs, we believe that the current audit process has consistently reviewed and treated approved off-cycle changes to MOCs (that is, off-cycle changes marked as approved or acceptable by NCQA) as acceptable. CMS will review and update our SNP audit protocols as warranted and CMS will consider feedback from stakeholders when determining if additional revisions are needed to ensure that CMS audits hold SNPs to their approved MOCs, including any approved changes to the MOCs.

Comment: A commenter did not support the proposal to include ''changes to quality metrics used to measure performance'' on the list of reasons requiring off-cycle submission and approval. The commenter noted that SNPs are required to conduct an annual quality improvement program that measures the effectiveness of its MOC. The commenter also stated that the goal of performance improvement and quality measurement is to improve the SNP's ability to deliver health services, improve member health outcomes, and increase organizational effectiveness. They noted that this includes examining current processes, including quality measures that should be modified. The commenter further noted that it may be necessary to change an entire quality measure to ensure that performance measures align with program goals and improve health outcomes. The commenter expressed that it would be an administrative burden to submit an off-cycle MOC for CMS approval of a change in quality metric(s) and that this submission requirement may have the effect of discouraging SNPs from making needed changes to their MOC, potentially impacting operational efficiencies and member health outcomes.

Response: We appreciate the commenter's suggestion, but we are not changing our policy on this topic. We believe it is important to review any changes to MOC quality metrics before such changes are implemented to ensure the operational integrity of the MOC by plans and so that SNPs are employing appropriate measurements so that NCQA can gauge the effectiveness overall of the MOCs implementation. As proposed and finalized here, the rule codified at § 422.101(f)(3)(iv)(B)(*3*) (that SNPs must submit off-cycle submissions based on changes to quality metrics used to measure performance) is from our long-standing off-cycle submission guidelines, and thus, a continuation of a policy that we believe SNPs are currently meeting. In addition, we note that the off-cycle revisions are for MOCs that SNPs have begun implementing after review and approval by NCQA; changing the quality metrics after performance has begun should also be reviewed to ensure that the changes in metrics are not designed to mask performance deficiencies or failure to implement the MOC as approved.

Comment: A commenter suggested that CMS increase the review capacity at NCQA to handle MOC reviews, especially off-cycle reviews in a timely, consistent, and effective way. They believe there should be a standard response timeline with standard, consistent, and timely communication. The commenter noted that a review should take no more than 30 days and the plans should be able to review the findings through an online portal.

Response: We do not believe that adopting a deadline for NCQA review of off-cycle MOC revisions would positively serve the MA program or lead to better or more efficient reviews of off-cycle submissions. NCQA already provides regular and timely review of off-cycle MOCs throughout the established review window. However,

we increasingly find that MA organizations that have many SNPs make a bulk submission of multiple changes to multiple MOCs (that is, making the same changes to multiple MOCs) at the end of the off-cycle window. When this occurs, it can cause some delay in NCQA's ability to finalize review of off-cycle submissions for all SNPs. We believe some SNPs struggled to find CMS' sub-regulatory guidance on significant versus non-significant changes and that this final rule will provide additional clarity in identifying when an off-cycle revision to an approved MOC is necessary. However, MA organizations that have a substantial number of off-cycle MOC submissions can avoid delays by submitting their MOCs at the beginning of the submission window timeframe, which is typically when fewer submissions have been received for review by NCQA. We also encourage, as a best practice, that MA organizations reach out to the Part C Policy mailbox prior to submission to provide notification to CMS and NCQA that the MA organization plans to submit a large bulk submission, as advance notice may assist NCQA to prepare and complete a more efficient review.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing new paragraph (f)(3)(iv) (for requirements on off-cycle changes to an approved MOC) largely as that regulation text was proposed but with modifications compared to our proposed regulation text. The modifications, listed here, are primarily to clarify and improve paragraph (f)(3)(iv):

In paragraph (f)(3)(iv), we are adding the text ''organization sponsoring'' between the proposed language ''An MA'' and ''a SNP that. . .'' for additional clarity. As finalized, the introductory language in paragraph (f)(3)(iv) reads: ''An MA organization sponsoring 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:'' This revision is clearer that the MA organization that offers the SNP is the legal entity responsible for the submissions.

In paragraphs (f)(3)(iv)(A) and (f)(3)(iv)(B), we are finalizing the paragraphs with revisions (described in more detail in a response to public comments earlier in this section) to clarify when off-cycle changes to an MOC must be submitted because CMS has directed the change to comply with applicable law and when off-cycle changes to an MOC must be submitted because of changes in how a D–SNP or I–SNP is administered or operates. As we noted earlier in this preamble, these changes are for additional clarity in the regulation.

We are also finalizing paragraph (f)(3)(iv)(B)(*1*) with organizational changes to make it easier to read and clearer that the standard ''substantial change'' applies to all of the listed areas. The areas under paragraph (f)(3)(iv)(B)(*1*) are now labeled as (i) the health risk assessment process; (ii) revising processes to develop and update the Individualized Care Plan (ICP); (iii) the integrated care team process; (iv) risk stratification methodology; and (v) care transition protocols. The revisions are more consistent with the intent of the proposal.

In paragraph (f)(3)(iv)(C), we have corrected the verb tense from ''will only review'' to ''only reviews.''

In paragraph (f)(3)(iv)(D), we are finalizing several changes to increase clarity in the regulation text but have not made substantive changes in policy. As finalized, paragraph (f)(3)(iv)(D)—in four sentences—clearly states that changes may not be made until NCQA has reviewed and approved the off-cycle changes and addresses how NCQA will review the changes. The first sentence states that SNPs may not make changes until NCQA has reviewed and approved the off-cycle MOC changes. A new second sentence states that NCQA does not rescore the MOC during the off-cycle process, but changes are reviewed and determined by NCQA to be either ''Acceptable'' or ''Non-acceptable.'' Two additional sentences follow to explain that ''Acceptable'' means that the changes have been approved by NCQA and the MOC has been updated; ''Non-acceptable'' means the changes have been rejected by NCQA and the MOC has not been changed; and that if NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved. These revisions are consistent with the proposal and the current process.

In paragraph (f)(3)(iv)(F), we are finalizing the provision to use ''permitted'' rather than ''eligible'' as it better reflects our current policy so that it now reads: ''C–SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.''

Finally, we are finalizing paragraph (f)(3)(iv)(G) to clarify the single opportunity for an SNP to submit a corrected off-cycle revision to the MOC if the initial off-cycle submission is not approved. The revisions generally use language that is consistent with § 422.101(f)(3)(iii)(C), which better signals that this part of the off-cycle revision process is similar to the cure period provided when the MOC submission is determined to have deficiencies. As finalized, paragraph (f)(3)(iv)(G) reads: ''When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.''

Although there were inadvertent differences in how the preamble of the proposed rule explained the proposed regulation text, we are finalizing the substance of our proposed policy for how off-cycle revisions to the MOCs of I–SNPs and D–SNPs could be requested and would be subject to review and approval before changes could be implemented.

C. Amending the Definition of Severe or Disabling Chronic Condition; Defining C–SNPs and Plan Types; and Codifying List of Chronic Conditions (§§ 422.2, 422.4(a)(1)(iv), and 422.52(g))

A specialized MA plan for special needs individuals, generally known as a special needs plan or a SNP, is an MA plan specifically designed to provide targeted care and limits 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 the special needs individuals eligible to enroll in C–SNPs. The amendments had an effective date of January 1, 2022, and included the following related to the revision of this definition: a directing 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; mandating the inclusion of several current C–SNP chronic conditions onto the list; and directing the Panel take into account the availability of benefits in the Medicare Advantage Value-Based Insurance Design model.

We proposed to codify the BBA of 2018's amendment to the definition of severe or disabling chronic condition; to codify the definition of C–SNP; to implement the BBA of 2018 by updating and codifying the recommended list of chronic conditions recommended by a Panel of clinical advisors as specified by the BBA; and to codify existing sub-regulatory guidance permitting the use of certain chronic condition combinations for the purposes of offering single standalone C–SNP plan benefit packages (PBPs).

A. Amending the Definition of Severe or Disabling Chronic Condition

Currently, § 422.2 defines ''severe or disabling chronic condition'' as meaning, for the purpose of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions 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. As summarized in more detail in the December 2022 proposed rule this definition was adopted to track amendments to section 1859(b)(6)(B)(iii) of the Act made by section 164(e) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) to define special needs individuals eligible for C–SNPs beginning January 1, 2010. (87 FR 79560) Section 164(e) of MIPPA also directed the Secretary to convene a Panel of clinical advisors to determine the chronic conditions used to identify special needs individuals for C–SNP eligibility. 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 16–B of the Medicare Managed Care Manual (MMCM). Starting in 2010, CMS adopted sub-regulatory 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-categorical conditions or disorders that provide further information regarding the types of diseases that qualify under the chronic condition categories. Examples of conditions with sub-categorical disorders include autoimmune disorders, cardiovascular disorders, severe hematologic disorders, chronic lung disorders, chronic disabling mental health conditions, and chronic disabling neurologic disorders. Currently, C–SNPs that target several of the severe or disabling chronic conditions listed in our guidance must enroll an eligible beneficiary who has one or more of the targeted conditions, including the 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 16–B where the special needs individuals may have one or more of the conditions in the grouping or (2) a MA organization-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 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 that the Secretary may determine would benefit from enrollment in such a specialized MA plan for individuals with severe or disabling chronic conditions 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].'' Section 1859(f)(9) of the Act, as added by the BBA of 2018, 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 each of the following criteria:

- Conditions that meet 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 conditions 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).

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.

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. 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 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 the following 22 chronic conditions as meeting the statutory criteria:

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.

We proposed to codify the list of chronic conditions created by the Panel as part of the definition of severe or disabling chronic condition at § 422.2. The proposal took into account the changes recommended by the Panel to the list of chronic conditions that are currently used by CMS to approve C–SNPs. These changes include:

• Removing the term ''limited'' in listing the severe or disabling chronic conditions that make an individual eligible to enroll in a C–SNP. 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 would 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 did not propose to use the word ''including'' in the proposed definition. We proposed 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;

• Renaming ''Chronic alcohol and other drug dependence'' to ''Chronic alcohol use disorder and other substance use disorders;''

• Adding 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;

• Adding valvular heart disease to the Cardiovascular disorders chronic condition category;

• Adding new chronic condition category, ''Overweight, Obesity, and Metabolic Syndrome;''

• Adding 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;

• Renaming 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;

• Adding Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD) to the Chronic lung disorders chronic condition category;

• Adding post-traumatic stress disorder (PTSD), eating disorders, and anxiety disorders to the Chronic and disabling mental health conditions category;

• Adding fibromyalgia, chronic fatigue syndrome, and spinal cord injuries to the Neurologic disorders conditions category;

• Adding post-organ transplantation care and immunodeficiency and immunosuppressive disorders as new chronic condition categories;

• Creating 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;

• Creating 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

• Creating new chronic condition category ''Conditions that require continued therapy services in order for individuals to maintain or retain functioning.''

As 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 proposed that C–SNPs would 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 as finalized will apply the same statutory and regulatory considerations per the parameters of a severe or disabling chronic condition and as noted in Title XVIII of the Act and 42 CFR part 422. In finalizing the three categories that are focused on impacts on health and functionality rather than underlying disease or condition, we are not eliminating the need for the effect on the enrollee to meet the statutory criteria in section 1859(f)(9) of the Act. As we noted in the December 2022 proposed rule, 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.

We received the following comments, and our responses follow:

Comment: Many commenters expressed general support for the list of chronic conditions; however, individual commenters provided specific support for certain additions to the list, such as: ''Dementia;'' the category ''Conditions that may cause cognitive impairment;'' ''chronic alcohol use disorder and other substance use disorders;'' chronic kidney disease (CKD); anxiety associated with chronic obstructive pulmonary disease (COPD); substance use disorders (SUD); chronic and disabling mental health conditions;; and the category ''Overweight, Obesity, and Metabolic Syndrome.'' There was also support for broadening the current set of chronic condition categories to a more holistic definition that accounts for the overall health and functional ability of an individual, including functional and cognitive needs. Commenters believe allowing enrollees with these conditions to enter into specialized C–SNPs will provide access to increased care coordination and improve health outcomes. Specifically, commenters who were supportive of adding CKD

noted that access to a specialized network of providers may prevent or slow disease progression toward ESRD.

Response: We appreciate the commenters support for these changes.

Comment: In responding to our solicitation of comment regarding the extent to which MA organizations would need more guidance with implementation of the proposed functional chronic condition categories, a commenter suggested that CMS take the approach of reviewing plan proposals for new C–SNPs organized around those functional categories and based on that experience, CMS should determine whether additional guidance is needed.

Response: We believe there is a great deal of merit to this suggestion. As CMS implements and operationalizes the new chronic condition list, we will assess whether additional guidance or information is needed to ensure compliance with the regulations (including those we are finalizing here) and the statute. Consistent with our current MA application procedures, all SNPs are currently required to submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance under 42 CFR 422.4(a)(1)(iv). CMS will consider the SNP's outline of care coordination activities as part of the MOC when determining whether additional guidance is necessary for submitting SNP applications under the new function-based C–SNPs.

Comment: A commenter suggested that CMS permit C–SNPs to offer plans that address the needs of beneficiaries, even if their specific disease or chronic conditions are different because it would an important step forward for integrated long-term care. The commenter notes that it is the needs of an individual, the activities of daily living (ADLs) and instrumental activities of daily living (IADLs) that should determine entry into a C–SNP, not the specific diagnosis.

Response: We appreciate the comment. It is unclear to us the specific needs the commenter believes should be addressed by defining the term severe or disabling chronic condition for purposes of establishing MA SNPs to address such conditions. As we noted in the December 2022 proposed rule, and in this final rule, the BBA of 2018 added requirements establishing chronic conditions. Section 1859(f)(9)(A) of the Act 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) of the Act; 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.

While we agree that the use ADLs and IADLs can assist health care providers and payers determine the health needs of patients, the Panel did not specifically create a chronic condition category around these measurements. As noted earlier in the preamble, the 2019 chronic condition Panel was limited to using these criteria when determining the content of the chronic conditions list. The Panel did recommend some function-based additions to the list that may be associated with conditions leading to deterioration of abilities, such as chronic condition (20) ''Conditions with functional challenges and require similar services including the following: spinal cord injuries, paralysis, limb loss, stroke, and arthritis.'' Because of these requirements, CMS does not have the authority to establish C–SNPs as suggested by the commenter at this time.

Comment: A commenter noted that Table D–A 1 on page 79566 of the December 2022 proposed rule showed that only one C–SNP focused on substance use disorders between 2007–2022. The commenter recommends CMS work with stakeholders to identify recommendations and guidelines that would make it easier for other MA organizations to redevelop and deliver such plans.

Response: We thank the commenter for their perspective. We acknowledge that few MA organizations have sponsored C–SNPs focusing on substance use disorders since the beginning of the program. CMS will review this request and determine whether we can employ informational outreach efforts or forums to encourage the use of underutilized chronic condition categories by organizations sponsoring C–SNPs. We encourage the public to provide additional information regarding the difficulties of creating certain condition-specific C–SNPs.

Comment: A commenter supported the adoption of the revised definition of ''Severe or Disabling Chronic'' Conditions and adding a new chronic condition category for ''Overweight, Obesity, and Metabolic Syndrome.'' The commenter urged CMS to use its authority to recognize that FDA-approved anti-obesity medications (AOMs) as clinically recommended treatments for a chronic disease—obesity, and may therefore be covered under Part D.

Response: We thank the commenter. However, the comment regarding AOMs and Part D coverage is out of scope for this rulemaking.

Comment: A commenter suggested that our proposed amendment to the definition of severe or disabling chronic condition reinforces the linkage between C–SNP and special supplemental benefits for the chronically ill (SSBCI) eligibility in that the same definition also is used for SSBCI eligibility determination in the BBA of 2018. The commenter stated that this may encourage more plans to use functional and cognitive needs to target SSBCI eligibility.

Response: We appreciate the comment, but CMS believes that the Act distinguishes the targeted beneficiaries of these benefits and programs in different ways that potentially limit the chronic conditions that may be employed between SSBCI and C–SNPs.

As defined in section 1852(a)(3)(D)(iii) of the Act, for the purposes of SSBCI, a chronically ill enrollee means an enrollee in an MA plan that the Secretary determines:

- has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
- has a high risk of hospitalization or other adverse health outcomes; and
- requires intensive care coordination.

CMS added this definition to our regulations at § 422.102(f)(1)(i)(A).

As we noted in the preamble to this final rule, the BBA of 2018 amended section 1859(b)(6)(B)(iii)(II) of the Act by adding a new definition of special needs individuals means an MA eligible individual who meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who 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 1859(f)(9)(A) of the Act.

The definition of chronically ill enrollee for the purposes of SSBCI is not specifically tied to the set of chronic conditions established by the Panel of clinical advisors under section 1859(f)(9)(A) as is the case for the definition of special needs individuals with ''severe or disabling chronic conditions'' that must be used in determining eligibility for C–SNPs. In addition, the definition of ''chronically ill enrollee'' in section 1852(a)(3)(D) of the Act does not include an assessment whether the Secretary determines the individual would benefit from enrollment in a specialized MA plan. CMS did not propose to specifically align eligibility for SSBCI with eligibility for C–SNPs and is not finalizing such a limitation for SSBCI in this rule. Rather, CMS proposed and finalized in the 2020 Final Rule (85 FR 33796) that for the purposes of SSBCI, the chronic conditions established by the Panel may be used to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee as required at 422.102(f)(1)(i)(A)(1). In the case of determining eligibility for SSBCI, MA plans are permitted to use other conditions not on the updated chronic condition list provided the condition is life threatening or significantly limits the overall health or function of the enrollee.

Comment: A commenter noted individuals that would be eligible for enrollment in a functional status-focused C–SNP would likely require robust functional, cognitive, and social determinants of health (SDOH) supports in addition to medical and behavioral health care services. The commenter expressed concerned that if enrollees in a functional-status focused C–SNP cannot access Medicaid funded LTSS, those enrollees would not fully benefit from this new C–SNP type. The commenter suggested that CMS work with stakeholders to identify new opportunities to provide appropriate and necessary functional and cognitive support services for this population, including SSBCI.

Response: We appreciate the comment and note that C–SNPs must have specific attributes that go beyond the provision of basic Medicare Parts A and B services and care coordination that is required of all coordinated care plans. For example, C–SNPs must develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with enrollee, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided to the enrollee. (See § 422.101.(f)(1)(ii)) Additionally, C–SNPs may offer supplemental benefits, including SSBCI, to provide a more robust set of items and services than offered under Traditional Medicare that are tailored to the needs of the plan population. C–SNPs do not have Medicaid integration requirements as some D–SNP plans do, as indicated in the definitions of FIDE SNPs and HIDE SNPs at § 422.2. While LTSS services may be available for individual C–SNP enrollees who are also enrolled in Medicaid, it is not currently a requirement that C–SNPs contractually integrate Part A/B services with Medicaid services offered by a state Medicaid agency or a Medicaid managed care plan that serves the same enrollee. However, coordination of services that are medically necessary for an enrollee and covered for that enrollee by Medicaid is an appropriate consideration for a C–SNP in developing the individualized plan of care for the enrollee. CMS understands that integration of Medicaid funded LTSS can be a great benefit to dually eligible beneficiaries, and we will continue to look at opportunities to service this population.

Comment: MedPAC specifically provided comment that they did not support the proposal to increase the number of chronic conditions under the proposed definition of severe or disabling chronic condition at § 422.2, nor do they support the current number of chronic conditions as listed in Chapter 16B of the MMCM. MedPAC noted that the Commission has long expressed concern that the list of conditions that C–SNPs can address was too broad and recommended that the list be narrowed. They stated that MA plans that are not C–SNPs should be able to manage most of the clinical conditions on the list; and that 95 percent of C–SNP enrollees are in plans that focus on just three conditions—cardiovascular disorders, diabetes, and chronic heart failure—that are relatively common in the Medicare population. In addition, MA plans now have the flexibility, through the MA Value-Based Insurance Design (VBID) demonstration and changes to the uniformity requirement, to target reductions in cost sharing and supplemental benefits to enrollees with specific conditions, which weakens the rationale for offering a separate set of plans that focus on a specific condition. Lastly, MedPAC stated that C–SNPs are only warranted for a small number of conditions, including HIV/AIDS, ESRD, and chronic and disabling mental illness.

Response: We note that the list of chronic conditions contained in the proposed definition of severe or disabling chronic condition under § 422.2, like the current list of chronic conditions listed in Chapter 16B of the Medicare Managed Care Manual, is based on the recommendations by the expert Panel of clinical advisors. As noted in the proposed rule, the proposed chronic condition recommendations were reviewed by a Panel of clinical advisors in accordance with subsection 1859(f)(9)(A) of the Act, as modified by the BBA 2018, as well as all other requirements set by statute (for the specifics of those requirements, please see 87 FR 79452). CMS concurs with the Panel's recommendations, and believes the Panel was in the best position to provide an objective assessment of what constitutes a severe or disabling chronic condition.

CMS recognizes that MA organizations have chosen to utilize a small subsegment of chronic conditions when establishing C–SNPs since the inception of the program. However, we believe following the Panel's recommendations of increasing the number of severe or disabling chronic conditions may encourage MA organizations to establish innovative approaches to comprehensive care for those with other severe or disabling chronic conditions.

We acknowledge that MA plans should be able to manage most of the clinical conditions on the list without the need to sponsor a disease-specific C–SNP. However, we reiterate the unique statutory and regulatory SNP care management and quality improvement requirements that are expected of C–SNPs established under section 1859(f) of the Act, and §§ 422.101(f) and 422.152(g). Currently, non-SNP MA plans are not required to meet these same standards. For example, the requirement at § 422.101(f)(1) that SNPs must implement a MOC and the requirements at § 422.101(f)(1)(ii) and (iii) to develop and implement an individualized care plan and interdisciplinary team, respectively, are not required of all MA plans (or even all MA coordinated care plans) and provide important additional benefits for the beneficiaries who are eligible for and enroll in C–SNPs.

With respect to the comment that C–SNPs are only warranted for a small number of conditions such as HIV/AIDS, ESRD, and chronic and disabling

mental illness, as noted previously, our decision to increase the number of chronic conditions on the list is based on the recommendations by the Panel of clinical advisors as mandated by statute. Importantly, the statute does not set numerical limits when considering conditions that should be on the list, rather the statute sets standards the Panel must consider when deciding the merits of any disease in fitting the definition of a severe or disabling chronic condition. When considering the composition of the list of chronic conditions, CMS follows the direction the Panel provides in utilizing the review conditions established by statute. Again, the Panel was asked to consider changes to the new definition of special needs individual, which is an eligible individual that the Secretary may determine would benefit from enrollment in such a specialized MA plan for individuals with severe or disabling chronic conditions 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].'' The Panel ensured that the updated definition speaks to the severity and medical complexity of the condition and its impact on the care considerations that the enrollee, their SNP care coordinator, and providers must navigate to optimize health outcomes for C–SNP enrollees.

Finally, we proposed in the December 2022 proposed rule that this new definition of severe or disabling chronic condition (that is, the new chronic condition list) would be applicable for plan years that begin on or after January 1, 2025, a delay of one additional year beyond the proposed applicability for most of the policies in that proposed rule. We proposed a delayed implementation of this for operational considerations and to allow plans and CMS to put in the place the necessary operational steps to permit transition from the current list of chronic conditions (and C–SNPs offered using that list) to the new definition and list of severe or disabling chronic conditions. Part of these considerations included the timing of MOC creation for C–SNPs that are due to CMS the February prior to upcoming contract year in which the MOC would take effect. After considering the gap in time between the issuance of the December 2022 proposed rule and the finalization of these provisions in the April 2024 final rule, we decided that it not necessary to delay the applicability of the new definitions for C–SNP and severe or disabling chronic condition under § 422.2 and the finalized rule at § 422.4 regarding groups of chronic conditions. This means that these rules will take effect with the effective date of this rule and be applicable beginning January 1, 2025. We acknowledge that C–SNP approval processes and MOC approval timelines mean that C–SNPs will not be able to effectively use this new definition to offer new C–SNPs until CY 2026 coverage. With the implementation of the new definition, several current chronic conditions would transition to new chronic condition categories, such as End Stage Renal Disease (ESRD) and End Stage Liver Disease. MA organizations seeking to establish a plan covering End Stage Liver Disease for CY 2026 would be able to do so under the new category of Chronic Gastrointestinal Disease. We also proposed a delay implementing the proposed new definition of severe or disabling chronic condition 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. We will move forward with the codification of the new definition of severe or disabling chronic conditions effective with the April 2024 final rule; however, CKD C–SNPs (like other conditions in the new list) will only be available starting with CY 2026. This allows CMS and plans time to review operational and bid considerations. At the time this final rule is issued, the MA rates for 2025 will have been (or will shortly be) released because MA rates for the next calendar year must be released the first Monday in April of the calendar year. Current ESRD C–SNPs plan bids are based on a distinct bidding methodology. CMS will provide additional bid pricing information to MA organizations consistent with current procedures.

After review of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed definition for the term ''severe or disabling chronic condition'' as proposed with minor modifications to the formatting of the regulatory text to improve the clarity of the definition.

B. 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 required of all coordinated care plans; such additional standards include the enrollment limitations, model of care, 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. See section HC.1 of this final rule regarding our finalization of a revised definition for the term severe or disabling chronic condition. 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. As we explained in the proposed rule, because the proposed definition was intended 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. The December 2022 proposed rule generally reflected current policy and practice, with a few modifications as discussed where applicable. As part of current C–SNP sub-regulatory guidance and during the MA plan application process, MA organizations 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 proposed, 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 a 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 proposed to codify how a C–SNP may focus on multiple chronic conditions in two ways. The proposed definition of C–SNP provided that the restricted enrollment to individuals with severe or disabling chronic conditions includes restricting enrollment based on the multiple commonly co-morbid and clinically linked conditions groupings specified in § 422.4(a)(1)(iv).

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.

Considering the established clinical connection between these conditions and the interest among plans and beneficiaries, we proposed to maintain the current policy. We proposed 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 several 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 proposed 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 proposed to add a new § 422.52(g) to clarify that enrollees need only have one of the qualifying conditions for enrollment listed in the approved groupings in proposed § 422.4(a)(1)(iv).[202] This is consistent with current CMS operational practices regarding the current set of approved C–SNP groups.

Lastly, CMS did not propose to codify a C–SNP plan application option that is currently available under sub-regulatory guidance in section 20.1.3.2 of Chapter 16B of the MMCM. In effect, this would remove this approach as an option for C–SNPs beginning 2025. 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 for this type of C–SNP 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 proposed 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 explained in the proposed rule that we believed 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.

We received the following comments, and our responses follow:

Comment: A commenter commended CMS for the changes to the list of severe or disabling chronic conditions under § 422.2; however, the commenter expressed concern that the further expansion of chronic condition groupings in proposed § 422.4(a)(1)(iv)(B) should be done in ways to minimize beneficiary and provider confusion, and to ensure conditions are clinically associated.

Response: We agree with the commenter that chronic conditions

[202] The December 2022 proposed rule inadvertently identified proposed § 422.4(a)(1)(iv)(A) as addressing this proposal that an enrollee of a C–SNP that focuses on a grouping of conditions would be required to only have one of the conditions to be eligible to enroll in that C–SNP; we use the correct reference here. 87 FR 79565.

should be clinically associated for a C–SNP that addresses multiple chronic conditions to be approved. As proposed and finalized here (at § 422.4(a)(1)(iv)(B)), consistent with current policy, a C–SNP may not be structured around multiple commonly co-morbid conditions that are not clinically linked in their treatment approaches and approved by CMS. As we noted in the December 2022 proposed rule, we believe that allowing a C–SNP to target a non-linked clinical arrangement results in a more general market product rather than a product that is tailored for a particular population. Further, as we stated in our proposed rule, 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 several 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. We believe the use of this process minimizes beneficiary and provider confusion and ensures that chronic condition groupings are clinically associated.

After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revised definition of the term ''chronic condition special needs plan (C–SNP)'' at § 422.2, the revisions to § 422.4(a)(1)(iv) to establish how C–SNPs may target specific and specific groupings of severe or disabling chronic conditions, and the special eligibility rule for C–SNPs at § 422.52(g) as proposed.

D. Verification of Eligibility for C–SNPs (§ 422.52(f))

Section 1859(b)(6) of the Act defines specialized MA plans for special needs individuals, as well as the term ''special needs individual.'' Section 1859(f)(1) of the Act provides that notwithstanding any other provision of Part C of the Medicare statute and in accordance with regulations of the Secretary, an MA special needs plan (SNP) may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals. The regulation governing eligibility for MA SNPs is at § 422.52. In addition to meeting the definition of a special needs individual in § 422.2 and the general eligibility requirements for MA enrollment in § 422.50, an individual must meet the eligibility requirements for the specific MA SNP in which the individual seeks to enroll. Currently, § 422.52(f) provides that each MA SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP. CMS adopted this provision in paragraph (f) in the final rule with comment period ''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 1494). Historically, we have provided operational guidance related to eligibility criteria for enrollment in an MA SNP that exclusively enrolls individuals who meet the definition of special needs individual under § 422.2 in our sub-regulatory manuals.[203]

We proposed to revise paragraph § 422.52(f) to codify, with minor modifications and clarifications, our longstanding guidance on procedural steps MA plans must take to verify an individual's eligibility for enrollment in a chronic condition SNP (C–SNP). C–SNPs are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined at § 422.2. By codifying the verification requirements, we intend to provide transparency and stability for MA organizations offering C–SNPs and other interested parties about this aspect of the MA program. It will also clarify the SNP's roles and responsibilities and further assist MA organizations in meeting the requirements pertaining to verification of eligibility for C–SNPs.

Specifically, we proposed in new § 422.52(f)(1) to codify existing guidance stating that for enrollments into a C–SNP, the MA organization must contact the individual applicant's current physician to confirm that the enrollee has the specific severe or disabling chronic condition(s). Although the current sub-regulatory guidance in chapter 16B, section 40.2.1 refers only to the applicant's existing provider, we believe that a physician—either the applicant's primary care physician or a specialist treating the qualifying condition(s)—should provide the required verification of the applicant's condition to ensure the accuracy and integrity of the verification process. Therefore, we proposed to use the term ''physician'' throughout proposed new § 422.52(f).

To further clarify the verification process, we also proposed in new § 422.52(f)(1)(i) that the physician must be the enrollee's primary care physician or specialist treating the chronic condition, or conditions in the case of an individual seeking enrollment in a multi-condition C–SNP. The MA organization may either 1) as proposed at new § 422.52(f)(1)(i), contact the applicant's physician or physician's office and obtain verification of the condition prior to enrollment, or 2) as proposed at new § 422.52(f)(1)(ii), use a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment and subsequently (which can be after enrollment) obtain verification of the condition(s) from the enrollee's physician no later than the end of the individual's first month of enrollment in the C–SNP.[204] Both proposed options are discussed in the current guidance. We continue to believe that these procedures will allow the MA organization to efficiently serve special needs populations while maintaining the integrity of SNP offerings under the MA program.

As part of this process, we proposed at new § 422.52(f)(1)(i) that verification of the chronic condition(s) from the applicant's primary care physician or treating specialist must be in a form and manner authorized by CMS. Existing guidance states that this verification can be in the form of a note from a provider or the provider's office or documented telephone contact with the physician or physician's office confirming that the enrollee has the specific severe or disabling chronic condition. These would remain acceptable under this proposal. Performing this pre-enrollment verification with the applicant's primary care physician or specialist treating the qualifying condition will mean that the C–SNP may process the enrollment promptly.

Use of the PQAT requires both pre-enrollment and post-enrollment actions by the C–SNP to conduct an assessment and subsequently confirm the information. The PQAT, per existing

[203] This guidance can be found at *https://www.cms.gov/files/document/cy2021-ma-enrollment-and-disenrollment-guidance.pdf* and *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16B.pdf.*

[204] CMS provides an outline of the Pre-enrollment Qualification Assessment Tool in section 40.2.1 of Chapter 16B of the MMCM. In 2017, CMS released a memo entitled, ''Discontinuation of CMS Approval Process for C–SNP Pre-Enrollment Qualification Assessment Tool,'' stating that we would no longer require chronic condition special needs plans (C–SNPs) to seek CMS approval prior to using a Pre-Enrollment Qualification Assessment Tool. CMS approval is granted for tools that meet the standards articulated in section 40.2.1 of the MMCM and individual review and approval of plan-specific tools is not required. Therefore, MA organizations are no longer required to submit these tools individually to CMS for approval so long as the standards outlined in the guidance are met.

guidance,[205] would collect information about the chronic condition(s) targeted by the C–SNP directly from the enrollee and must include a signature line for a physician to confirm the individual's eligibility for C–SNP enrollment. In order for the PQAT to be complete, a physician must be the person who goes through the PQAT with the enrollee. The physician that goes through the PQAT with the enrollee can be either the enrollee's physician or a physician employed or contracted by the plan. A physician must later review the document to confirm that the information supports a determination that the enrollee is eligible for the C–SNP, even without their presence at the time of the determination by the physician. The physician providing the review and signature must be the enrollee's physician. Ultimately, a physician's review of and signature on the completed PQAT provide verification of the applicant's special needs status with regards to the applicable chronic condition(s). Currently, C–SNPs are not required to submit the PQAT to CMS for review and approval before the PQAT is used by the C–SNP and CMS proposed to codify that policy. The PQAT must meet the standards articulated in proposed § 422.52(f)(1)(ii)(A), and therefore review and approval of plan-specific tools by CMS are not required.

- As proposed at § 422.52(f)(1)(ii)(A)(*1*), the PQAT must include a set of clinically appropriate questions relevant to the chronic condition(s) on which the C–SNP focuses. For example, an MA organization sponsoring a Diabetes Mellitus C–SNP would perhaps include questions related to diagnoses of diabetes, such as blood glucose level or whether the enrollee is currently taking a medication for diabetes mellitus.
- As proposed at § 422.52(f)(1)(ii)(A)(*2*), the PQAT must gather information on the applicant's past medical history, current signs and/or symptoms, and current medications sufficient to provide reliable evidence that the applicant has the applicable condition(s).
- As proposed at § 422.52(f)(1)(ii)(A)(*3*), the PQAT must include the date and time of the assessment if completed during a face-to-face interview with the applicant, or the receipt date if the C–SNP receives the completed PQAT by mail or by electronic means (if available).
- As proposed at § 422.52(f)(1)(ii)(A)(*4*), the PQAT must include a signature line for and be signed by a physician to confirm the individual's eligibility for C–SNP enrollment. (We also proposed that this signature be from the applicant/enrollee's primary care physician or treating specialist.)
- As proposed at § 422.52(f)(1)(ii)(B), the C–SNP must conduct a post-enrollment confirmation of each enrollee's information and eligibility using medical information (medical history, current signs and/or symptoms, diagnostic testing, and current medications) provided by the enrollee's primary care physician or the specialist treating the enrollee's chronic condition.
- As proposed at § 422.52(f)(1)(ii)(C), the C–SNP must include the information gathered in the PQAT and used in this verification process in the records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.
- As proposed at § 422.52(f)(1)(ii)(D), the C–SNP must track the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment and the data and supporting documentation must be made available upon request by CMS.

In addition, we proposed to codify at § 422.52(f)(1)(ii)(E) our longstanding guidance [206] to MA organizations offering C–SNPs that choose to use a PQAT that the MA organization has until the end of the first month of enrollment to confirm that the individual has the qualifying condition(s) necessary for enrollment into the C–SNP. If the C–SNP cannot confirm that the enrollee has the qualifying condition(s) within that time, the C–SNP has the first seven calendar days of the following month (that is, the second month of enrollment) in which to send the enrollee notice of disenrollment for not having the qualifying condition(s). Disenrollment is effective at the end of the second month of enrollment; however, as also outlined in current guidance, the C–SNP must continue the individual's enrollment in the C–SNP if confirmation of the qualifying condition(s) is obtained at any point prior to the end of the second month of enrollment. We proposed to codify at § 422.52(f)(1)(ii)(F), consistent with existing guidance, that the C–SNP must continue the enrollment of the individual in the C–SNP if the C–SNP confirms the qualifying condition(s) prior to the disenrollment effective date.

Lastly, we proposed to codify at § 422.52(f)(1)(iii) that the C–SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C–SNP. Once the physician has confirmed that the PQAT contains information that supports the applicant's chronic condition and signs it, the PQAT is complete. Without a physician's signature, the process is incomplete, and thus, the applicant must be denied enrollment if the enrollment has not yet happened or disenrolled by the end of the second month if the applicant had been enrolled. If the individual is disenrolled because the person's eligibility cannot be verified, SNPs must recoup any agent/broker compensation consistent with § 422.2274(d)(5)(ii).

These proposals represent the codification of existing guidance outlining the procedural steps MA organizations currently take to verify an individual's eligibility for enrollment in a C–SNP, with minor modifications and clarifications. Therefore, we believe that this proposal would not result in a new or additional paperwork burden, as the policy to verify eligibility for C–SNPs has been in existence for some time. All burden impacts related to the SNP eligibility verification procedures have already been accounted for under OMB control number 0938–0753 (CMS–R–267). These requirements have been previously implemented and are currently being followed by MA organizations. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: Several commenters expressed general support but recommended using a term other than ''physician'' when referring to the activities that must be completed to confirm a beneficiary's eligibility for the C–SNP. Commenters noted that many individuals receive treatment for their chronic condition from other providers (*e.g.,* nurse practitioners, physician assistants) and that by limiting the verification functions to the beneficiary's current physician, we were establishing a requirement that was too restrictive, would add operational

[205] This guidance can be found in Chapter 16–B: Special Needs Plans, Section 40.2 of the Medicare Managed Care Manual.

[206] This guidance can be found in Chapter 2, Section 20.10 and Chapter 16–B: Special Needs Plans, Section 40.2 of the Medicare Managed Care Manual.

complexity, and create procedural barriers that obstruct beneficiaries' access to needed healthcare. Commenters also stated that physicians may not provide timely verification in response to a direct request or a PQAT which affects a C–SNPs' ability to swiftly seek data to verify beneficiaries' conditions.

Commenters suggested that CMS codify a sufficiently broad term to allow a variety of healthcare professionals with requisite qualifications to confirm the applicant's specific severe or disabling chronic condition(s). Examples include the following terms: ''health care provider'' or ''practitioner'' to include those who work in clinic environments and any clinical staff in the physician's office, (*e.g.,* registered nurses), which would align with existing verification protocols and will enable MA plans to offer and enroll beneficiaries with chronic conditions in plans best suited to meet their healthcare needs and preferences more efficiently. Another commenter further suggested that an alternate person at the provider practice be able to conduct this administrative function on behalf of the provider so as to not create more administrative burden and also facilitate enrollment. Another commenter stated that CMS uses the term ''provider'' for confirming the patient has a qualified condition in its existing guidance.

Response: We appreciate the feedback and agree that the term ''physician'' may be overly restrictive or may not accurately reflect a beneficiary's overall care team. As such, we are modifying § 422.52(f)(1) to replace the term ''physician'' with language describing the three types of health care providers we believe are appropriate to furnish confirmation that an enrollee has a severe or disabling chronic condition: (1) a physician, as defined in section 1861(r)(1) of the Act; (2) a physician assistant, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c); or (3) a nurse practitioner, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii). The modification will permit physician assistants and nurse practitioners who meet the specified qualification to provide the type of verification required under § 422.52(f).

The definition of physician in section 1861(r)(1) of the Act is defined to mean a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the individual performs such functions or actions. Although CMS proposed that all physicians within the scope of the definition of section 1861(r) of the Act would qualify for purposes of the proposed requirements for verifying eligibility to enroll in a C–SNP, we believe it is more appropriate to limit this to physicians as defined in section 1861(r)(1) to be more consistent with and reflect our current subregulatory policies regarding chronic condition verification and our intent with codification of this policy. Because section 1861(r)(1) of the Act includes all doctors of medicine or osteopathy who are legally authorized to practice medicine and surgery by the State in which the individual performs such functions or actions, using ''physician'' as meaning this group is sufficiently broad for purposes of verifying that an individual has a specified severe or disabling chronic condition. Per section 1861(aa)(5)(A) of the Act, the terms ''physician assistant'' and ''nurse practitioner'' mean a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations. Therefore, in addition to citing section 1861(aa)(5)(A) of the Act, we are also cross-referencing the additional Medicare regulations (§§ 410.74(c) and 410.75(b)(1)(i) and (ii)) that specify the qualifications for a physician assistants and nurse practitioners to define these providers.

In addition to these changes we are finalizing in § 422.52(f)(1), we are also finalizing changes throughout § 422.52(f) to replace the term ''physician'' with the phrase ''health care provider'' or ''health care provider specified in paragraph (f)(1)'' to be consistent with our final policy that physicians, physician assistants, and nurse practitioners may furnish the necessary verification. We use the term ''health care provider'' to avoid unintended ambiguity or confusion that § 422.52(f) is using the term ''provider'' as it is defined broadly in § 422.2. In addition, we are finalizing paragraph (f)(1)(iii) with revisions to specify that the PQAT must be signed by the enrollee's current health care provider as verification and confirmation that the enrollee is eligible for the C–SNP, especially as a provider employed or contracted by the plan may administer the PQAT with the enrollee. We believe allowing a SNP to use a provider employed or contracted by the plan permits operational flexibility without jeopardizing the independent verification of the applicant's condition. For example, a SNP may employ a registered nurse to administer the PQAT with the applicant that will then receive independent verification from the applicant's health care provider. CMS understands that establishing the same criteria for administering the PQAT under 422.52(f)(1)(ii)(B), as we propose under § 422.52(f)(1) for health care provider verification, would likely create operational burdens for SNPs. We are finalizing the revised process at paragraph (f)(1)(iii) that both acknowledges the potential burden to plans, but also ensures that the applicant's health care provider is still verifying of the existence of the chronic condition.

Comment: We received several comments pertaining to the PQAT. While commenters supported CMS' need to verify eligibility, several suggested the use of alternative data to support post-enrollment verification in lieu of the PQAT. For example, the use of existing institutional documentation, specifically the Minimum Data Set (MDS), to serve as documentation of a beneficiary's qualifying condition and the use of medical and pharmacy claims data to verify a C–SNP enrollee's chronic condition in cases where the enrollee's provider is unresponsive. Some commenters expressed concerns regarding the administrative challenges of acquiring a signature on the PQAT form, processing disenrollment due to a failure to obtain the required physician verification, and reliance on the information submitted by the beneficiary, which runs the risks of inaccuracies. Another commenter suggested that plans using the PQAT and post-enrollment verification process should be able to use the health care provider's verification via a recorded phone outreach, signature on the PQAT form, data from the enrollee's electronic health records, or other diagnoses received directly from the enrollee's provider. Some commenters were concerned that the proposal could disincentivize new or smaller MA organizations from establishing C–SNPs to offer coverage and care for this vulnerable population.

Response: We appreciate the suggestions for alternative methods to verify that a C–SNP applicant has a qualifying severe or disabling chronic condition. However, the applicant's current health care provider plays a critical role in verifying the beneficiary's chronic condition. We

believe that review by the applicant's current health care provider is an important step to maintain C–SNP program integrity and the involvement of a health care provider who has a current relationship with the applicant and is not an employee of the C–SNP (or of the MA organization that offers the C–SNP) reduces burden when compared to alternatives such as seeking an independent evaluation of the applicant from another health care provider. We reiterate that the MA organization may contact the applicant's current health care provider or that provider's office to obtain verification of the condition prior to enrollment and that the use of the PQAT is an optional substitute prior to enrollment. The MA organization is allowed additional time (post-enrollment) to obtain verification from the applicant's current provider if the MA organization elects to use the PQAT prior to enrollment in lieu of getting confirmation from the applicant's current health care provider (or that provider's office), as further clarified in 422.52(f)(1)(iii) and 422.52(f)(1)(ii)(B). We believe limiting the verification confirmation process to this group of providers best aligns with those providers most likely to diagnose and treat the type of severe or disabling chronic condition listed in the definition of that term being adopted elsewhere in section VIII.C. of this rule. We note that the proposal is the codification of long-standing guidance in Chapter 16–B with minor modifications. The rule as finalized does not prohibit plans from consulting data or records of the type mentioned by the commenters, but data review alone cannot be a method of independent verification, which only the applicant's current provider's review and signature can impart. As further clarified in 422.52(f)(1)(ii)(A)(*4*), the completed PQAT must be signed by the applicant's current health care provider. We are including the phrase ''once completed'' in the regulation to clarify that the health care provider would be signing the PQAT as filled in with the applicant's information as a means to verify the PQAT; blank PQAT forms should not be signed in advance.

Comment: A commenter expressed concerns that CMS' proposal created a requirement that plans must rely on a prior eligibility verification from another plan for purposes of enrollment in a C–SNP. The commenter preferred to conduct its own eligibility verification to ensure it has accurate and current information about beneficiaries.

Response: We believe the commenter misunderstood the proposal as we did not propose to require and currently do not require C–SNPs to rely on a prior verification of eligibility information from a previous plan. The opposite is the case. Under the rule we are finalizing and our current policy, C–SNPs cannot use a previous plan's chronic condition verification for the purpose of verifying an applicant's eligibility into their plan. Each C–SNP must conduct its own verification that the applicant has a qualifying severe or disabling chronic condition as outlined in § 422.52(f)(1).

Comment: A commenter suggested making the proposed changes effective no sooner than the 2026 plan year to provide sufficient time to implement the operational changes which they deemed as significant.

Response: We decline the suggestion to make the effective date later because the proposal is codifying longstanding guidance and plans should currently be performing these activities in compliance with our sub-regulatory guidance. To the extent that we are finalizing changes compared to our current guidance (for example, the expansion of the type of provider that can furnish the verification), we do not believe that these changes will add burden or make the process for verifying eligibility for new enrollees more difficult. The provisions we are finalizing at § 422.52(f) regarding eligibility verification for C–SNP enrollees are applicable with coverage beginning January 1, 2025.

Comment: A commenter believed that the PQAT is a duplicative assessment and adds unnecessary reporting burden since plans already request and document similar information as part of conducting a Health Risk Assessment (HRA) after enrollment.

Response: We agree that the HRA requirements under § 422.101(f)(1)(i) and the PQAT requirements being finalized under § 422.52(f)(1)(ii)(A)(1) may appear to collect similar health information. While there may be some similarities between the HRA and PQAT processes, the HRA is more specific in the categories of information collection (psychosocial, functional, etc.) and the PQAT is more specific to the severe or disabling chronic condition(s) the MA organization is required to verify prior to enrollment into a C–SNP. These tools serve different purposes, are not interchangeable, and are not duplicative, even if there is potential crossover in some of the information that is captured. We note that the PQAT is one of two ways to verify C–SNP eligibility prior to enrollment and that its use is optional.

Comment: A commenter noted that many C–SNP applicants are not new to an MA plan, but they are instead transferring from a non-SNP plan offered by the same MA organization with the same provider network. The MA organization may already have medical professionals (such as nurse practitioners and physician assistants) working with the member on ongoing condition management through clinical programs available from the non-SNP and clinical program staff may already be coordinating with the member's primary care provider or other physicians. The commenter stated that requiring the member's physician to once again validate to the MA organization that the member has the qualifying condition for enrollment in the C–SNP seems unnecessary and an inefficient use of the physician's (or physician's staff) time. The commenter requested that CMS continue to allow confirmations from a ''plan provider qualified to confirm the condition.''

Response: We believe that the review and sign-off by the applicant's current health care provider, who is already familiar with the MA organization's operational methods, will not add burden or create inefficiencies. The review by the applicant's current health care provider is a critical step in ensure program integrity of the C–SNP verification process. As discussed in a prior response to a public comment, we are finalizing § 422.52(f)(1) to permit the verification to be provided using the applicant's current health care provider, who is a physician (as defined in section 1861(r)(1) of the Act), physician assistant (as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c) of this chapter), or a nurse practitioner (as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii) of this chapter) to confirm that the applicant has the qualifying condition(s); by including physician assistants and nurse practitioners who are also currently treating the applicant, we believe that we are sufficiently addressing concerns about burden on physicians. In addition, as finalized, pre-enrollment verification may be provided by the C–SNP contacting the treating health care provider directly or the treating health care provider's office; we believe that the treating health care provider's office would be able to use information in the applicant's records to provide sufficient information to verify that the applicant has the qualifying severe or disabling chronic condition in many if not all cases. Further, although paragraphs (f)(1)(ii)(B) and (f)(1)(iii) require the

enrollee's current health care provider to sign the PQAT as verification of the information used to establish eligibility, the C–SNP will have until the second month of enrollment to secure the signature as reflected in paragraphs (f)(1)(ii)(E) and (F), which we believe provides sufficient time post-enrollment to minimize the burden on the health care provider.

Comment: A commenter requested that in situations where an individual is disenrolled due to an inability to verify their eligibility, the deadline for disenrollment deadline be extended from 60 days to 90 days to align with the HRA completion deadline.

Response: We disagree that the standard is too restrictive as the proposed timeline is consistent with long-standing guidance in Chapter 16–B and C–SNPs have consistently shown the ability to meet this timeline. We also make the distinction that the verification process establishes the individual's eligibility, whereas the HRA completion assumes the applicant's eligibility and focuses on care coordination.

Comment: A commenter noted that under Special Supplemental Benefits for the Chronically Ill (SSBCI), plans can provide health-related and non-health-related benefits targeted to enrollees with C–SNP conditions in non-SNP plans, with significantly less documentation of an enrollee's condition than required for C–SNP enrollment. The commenter stated that requirements that place significantly higher barriers for C–SNP enrollment versus SSBCI eligibility can be detrimental to an individual seeking to switch to a C–SNP plan because they want more comprehensive case management and clinical support. Further, when validations are not received and individuals are disenrolled, the stress and disruption in care experienced by members can also exacerbate their health issues, which is the opposite of what they are seeking when they apply for the C–SNP. Limiting the diagnosis validation requests made to physicians for those members who are new to the MA plan or who are new to Medicare, would be a more effective use of time and resources for both the plan and providers, and would reduce the number of members who are disenrolled for administrative reasons. The commenter encouraged CMS to consider whether those differences support optimal outcomes for members with ongoing chronic conditions.

Response: We appreciate the comment. To the extent that an MA organization adopts a similar process for verifying eligibility for SSBCI under § 422.102(f)(4) as what is required by § 422.52(f)(1) as finalized here, it may be possible to rely on the verification by the individual applicant's/enrollee's health care provider or on the PQAT and subsequent confirmation for both purposes if the verification of eligibility for the C–SNP and for the SSBCI occur very close in time. However, § 422.102(f)(4) does not establish the same verification requirements as we are finalizing in § 422.52(f)(1), so it is not appropriate to develop a sweeping exception from either §§ 422.52(f)(1) or 422.102(f)(4). For more information on § 422.102(f) and SSBCI, we refer readers to section I.B.4 of this final rule. A non-SNP MA plan is a more generalized MA product that can offer SSBCI under § 422.102(f). CMS reviews whether an MA organization can deliver care under specific SNP regulations, including whether a plan can deliver care coordination and benefit arrangements for a specific chronic condition population. We believe it is critical to establish the specific processes of the C–SNP applicant verification to ensure the integrity of C–SNP plan operations.

Comment: A couple of commenters were concerned that the burden ultimately falls on the beneficiary to ensure that the provider responds to a plan's verification request in order to ensure they are able to enroll in their chosen plan. Because some providers will not submit the pre-enrollment attestation without an office visit, the proposed requirement could mean that a beneficiary that has recently seen their physician might need to visit their physician again solely for pre-enrollment verification purposes.

Response: We recognize that in some instances the applicant's health care provider could potentially ask the applicant to schedule an office visit before the health care provider will verify that the applicant has a qualifying severe or disabling chronic condition for the C–SNP. We believe that this is unlikely based on our knowledge of how this policy has played out historically and by the fact that the applicant's current health care provider's office will likely have information pertaining to the relevant medical history to verify the chronic condition.

Comment: A commenter noted that when considering pre-enrollment verification requirements, CMS must guard against providers who potentially may be incentivized to use C–SNP pre-enrollment verification as a tool in steering the beneficiary to a plan associated with the provider but may not be in the best interest of the beneficiary. The commenter stated that under the pre-enrollment verification process, it would be difficult to ensure that an enrollee's current treating physician will verify that an enrollee has a qualifying severe or disabling chronic condition in a timely manner if they know the enrollee is considering enrollment in a plan with which the provider does not contract.

Response: We appreciate the commenter's concern and acknowledge that such scenarios may occur. We believe that this is unlikely based on our knowledge of how this policy has played out historically.

After consideration of all public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal to add new paragraph (f)(1) to § 422.52 largely as proposed, but with modifications to specify that an applicant's current health care provider, who may be a physician, nurse practitioner or physician's assistant, provides the verification of the applicant's chronic condition. In addition, as described in our responses to public comments, we are finalizing revisions in paragraphs (f)(1)(i), (f)(1)(ii)(A)(4), (f)(1)(ii)(B) and (f)(1)(iii) to be consistent with the revisions in paragraph (f)(1) and to clarify the post-enrollment verification process when the C–SNP uses the PQAT.

E. I–SNP Network Adequacy

In accordance with § 422.116, CMS conducts evaluations of the adequacy of provider networks of all MA coordinated care plans to ensure access to covered benefits for enrollees. For MA coordinated care plans, which generally base coverage or cost sharing on whether the provider that furnishes services to an MA enrollee is in-network or out-of-network, these evaluations are particularly important. All MA special needs plans (SNP) are coordinated care plans and subject to the current requirements for network adequacy. Within the MA program, SNPs are classified into three distinct types: Chronic Care special needs plan (C–SNP), dual eligible special needs plan (D–SNP), and Institutional special needs plan (I–SNP). An I–SNP is a SNP that restricts enrollment to MA-eligible individuals who meet the definition of institutionalized and institutionalized-equivalent. One specific subtype of I–SNP is the facility-based I–SNP. Here, we use the term (''facility-based I–SNP'') to refer to an 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 § 422.2, for each county within the plan's county-based service area; and owns or has a contractual arrangement with each institutional facility serving enrollees in the plan. Historically, the I–SNP industry has stated that CMS's current network adequacy criteria under § 422.116 create challenges for facility-based I–SNPs because facility-based I–SNP enrollees access services and seek care in a different way than enrollees of other plan types.

In the December 2022 proposed rule, we explained in detail how I–SNPs restrict enrollment to MA-eligible individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in § 422.2 and proposed new definitions for the different types of I–SNPs. As a result, the enrollees in I–SNPs are individuals who continuously reside in or are expected to continuously reside for 90 days or longer in one of the specified facilities listed in the definition of ''institutionalized'' at § 422.2 or individuals (''institutionalized-equivalent'') who are living in the community but require an institutional level of care. We refer readers to the December 2022 proposed rule (87 FR 79566 through 79568) and to section VIII.A of this final rule for a more detailed discussion of the eligibility requirements for I–SNPs and the final rule definitions for the different type of I–SNPs. See also Chapter 16b Section 20.3 of the Medicare Managed Care Manual.[207] Our use of the term ''facility-based I–SNP'' in this rule aligns with the definition of ''Facility-based Institutional special needs plan (FI–SNP)'' adopted in section VIII.A of this rule.

Per section 1859(f)(2) of the Act, I–SNPs restrict enrollment to MA-eligible individuals who, for 90 days or longer, have had or are expected to need the level of services provided in a long-term care (LTC) facility, which includes: a skilled nursing facility (SNF), a nursing facility (NF), an intermediate care facility for individuals with intellectual disabilities (ICF/IDD), an inpatient psychiatric hospital, a rehabilitation hospital, an LTC hospital, or a swing-bed hospital. See § 422.2 for the definition of ''institutionalized'' for the details of the types of facilities. Facility-based I–SNPs (FI–SNPs) serve a vulnerable cohort of Medicare beneficiaries with well over 95 percent of FI–SNP enrollees being eligible for both Medicare and Medicaid. Generally, FI–SNP enrollees reside either temporarily or permanently in an institution, therefore, these enrollees typically receive most of their health care services through or at the facility in which they reside, most often a SNF. As a result of the way that these enrollees receive covered services, CMS's established network adequacy time and distance standards under § 422.116 may not be a meaningful way to measure provider network adequacy for and ensure access to covered benefits for enrollees of this plan type. Time and distance standards are created using several factors, including pattern of care. In order to comply with the network evaluation requirements in § 422.116, a FI–SNP must contract with sufficient providers of the various specialties within the time and distance requirements specified in that regulation. The I–SNP industry has indicated through public comments and in prior correspondence to CMS that many FI–SNPs have difficulty contracting with providers outside their facilities, due to their model of care. This is because these providers know that enrollees of the I–SNP will not routinely seek care with these providers since they generally do not travel away from the facility for care.

The MA organizations offering and those that are interested in offering FI–SNPs have raised questions about whether our network standards are appropriate considering the nature of the FI–SNP coverage model. The residential nature of this model creates inherent differences in patterns of care for FI–SNP enrollees as compared to the prevailing patterns of community health care delivery in other MA plan types. For example, most residents of a facility receive their care from a provider at the facility rather than traveling to a provider outside the facility whereas individuals who live at home in the community will need to travel to a provider to receive health care services.

To address these concerns, CMS proposed to adopt a new exception for FI–SNP plans from the network evaluation requirements. This provision will apply only to FI–SNPs.

CMS adopted minimum access requirements for MA coordinated care plans (which include all SNPs) in § 422.112 and network evaluation criteria in § 422.116 as means to implement and ensure compliance with section 1852(d)(1)(A) of the Act, which permits MA plans to limit coverage to items and services furnished by or through a network of providers subject to specific exceptions (such as emergency medical services) and so long as the MA organization makes benefits available and accessible to their enrollees. Currently, § 422.116(f) allows an MA plan to request an exception to network adequacy criteria when both of the following occur: (1) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file (that is, a cross-sectional database that includes information on provider and facility name, address, national provider identifier, and specialty type and is posted by state and specialty type); and (2) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. In evaluating exception requests, CMS considers whether: (i) the current access to providers and facilities is different from the Health Service Delivery (HSD) reference file (as defined at 42 CFR 422.116(a)(4)(i)) and Provider Supply files for the year; (ii) there are other factors present, in accordance with *§ 422.112(a)(10)(v),* that demonstrate that network access is consistent with or better than the Traditional Medicare pattern of care; and (iii) the approval of the exception is in the best interests of beneficiaries.

CMS has provided examples of situations that meet the first requirement for an exception to be requested in sub-regulatory guidance, specifically the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance.[208] The following examples of situations where providers or facilities are not available to contract with the MA plan do not account for the issues that are unique to FI–SNPs:

- Provider is no longer practicing (for example, deceased, retired),
- Provider does not contract with any organizations or contracts exclusively with another organization,
- Provider does not provide services at the office/facility address listed in the supply file,
- Provider does not provide services in the specialty type listed in the supply file,
- Provider has opted out of Medicare, or
- Provider is sanctioned and on the List of Excluded Individuals and Entities.

In addition, the use of Traditional Medicare telehealth providers or mobile providers and the specific patterns of care in a community that currently are

[207] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.*

[208] *https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance08302022.pdf.*

the basis for an approval exception do not account for the provider network issues unique to FI–SNPs that we proposed to address in this rule. Therefore, we proposed to amend our network adequacy regulations at § 422.116(f) to establish an additional exception to the current CMS network adequacy requirements outlined in § 422.116 and we proposed that this exception be specific to FI–SNPs. As proposed and finalized, the revisions to § 422.116 provide that FI–SNPs will not be required to meet the current two prerequisites to request an exception from the network adequacy requirements in § 422.116 but FI–SNPs must meet alternate bases on which to request an exception.

With respect to the exceptions from the network adequacy process for FI–SNPs, CMS proposed to broaden the acceptable rationales for an exception from the requirements in § 422.116(b) through (e) for FI–SNPs. We proposed that a FI–SNP may request an exception from the network adequacy requirements in § 422.116 when one of two situations occurs. To add these proposed new rationales to § 422.116(f)(1), we proposed to reorganize the current regulation text; the two current requirements for an exception request will be moved to new paragraphs (f)(1)(i)(A) and (B) and the proposed new rationales for an exception request will be in new paragraphs (f)(1)(ii)(A) and (B). Next, we proposed additional considerations CMS will use when determining whether to grant an exception under § 422.116(f) that are specific to the additional acceptable rationales we proposed for an exception request. We proposed to add a new paragraph (f)(2)(iv) to specify the proposed new considerations that will apply to the new exceptions for FI–SNPs, which will be added to the existing considerations in § 422.116(f)(2).

This provision includes new bases on which only FI–SNPs may request an exception from the network adequacy requirements, additional considerations for CMS when deciding whether to approve an exception request from a facility-based I–SNP, and a new contract term for FI–SNPs that receive the exception from the § 422.116 network adequacy evaluation. Because we evaluate network adequacy and grant an exception at the contract level, this new exception is limited to contracts that include only FI–SNPs.

The first new basis on which we proposed a FI–SNP could request an exception from § 422.116(b) was that the FI–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in FI–SNPs receive care. For purposes of this first proposed new basis for an exception, the inability to contract means the MA organization offering the FI–SNP could not successfully negotiate and establish a contract with a provider, including individual providers and facilities. This new basis is broader than the existing condition for an exception that certain providers are unavailable for the MA plan (see current § 422.116(f)(1)(i), which we are redesignating to § 422.116(f)(1)(A) in this final rule). The non-interference provision at section 1854(a)(6) of the Act prohibits CMS from requiring any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, CMS cannot assume the role of arbitrating or judging the bona fides of contract negotiations between an MA organization and available providers or facilities. CMS does not regard an MA organization's inability to contract with a provider as a valid rationale for an exception from the network adequacy evaluation, but interested parties have indicated through public comments and in prior correspondence to CMS outside this particular rulemaking process that, historically, FI–SNPs have encountered significant struggles contracting with the necessary number of providers to meet CMS network adequacy standards due to their unique care model. In the proposed rule, we explained that we would add this new basis for an exception request to § 422.116(f)(1)(ii)(A). CMS also proposed that its decision whether to approve an exception for a FI–SNP on this specific basis (that the I–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in FI–SNPs receive care) will be based on whether the FI–SNP submits evidence of the inability to contract with certain specialty types required under § 422.116 due to the way enrollees in FI–SNPs receive care. For example, an organization could submit letters or emails to and from the providers' offices demonstrating that the providers were declining to contract with any FI–SNP. CMS proposed to add this requirement in a new paragraph (f)(2)(iv)(A). CMS will also consider the existing factors in addition to the new factors proposed here that are unique to the specific new exception proposed for FI–SNPs. In the proposed rule, we solicited comment on this proposed new rationale for an exception from the network adequacy requirements in § 422.116(b) through (e) and on the type of evidence we should consider in determining whether to grant an exception.

We also proposed a second basis on which a FI–SNP may request an exception from the network adequacy requirements in § 422.116(b) through (e) if:

(1) A FI–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135 of this chapter) when using telehealth providers of the specialties listed in paragraph (d)(5) in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e); and

(2) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135 of this chapter) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the FI–SNPs covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2) of this chapter, with in-network cost sharing for the enrollee.

We believe it is appropriate to permit exceptions to the network evaluation standards in § 422.116(b) through (e) in these situations because enrollees in FI–SNPs do not generally travel to receive care, so the time and distance standards that apply to other plan types are not appropriate for I–SNP plans. As part of this proposal, we proposed to add to the factors that CMS will consider whether to approve the exception request a new factor specifically related to this type of exception.

Finally, we proposed new regulation text to ensure that the exception for FI–SNPs is used by and available only to FI–SNPs. We proposed a new paragraph (f)(3) at § 422.116 to require any MA organization that receives the exception provided for FI–SNPs to agree to offer only FI–SNPs on the contract that receives the exception. To support the provision outlined at § 422.116(f)(3), CMS also proposed to add, at § 422.504(a)(21), a new contract provision that MA organizations must not establish additional plans (or plan benefit packages, called PBPs) that are not facility-based I–SNPs to a contract that is within the scope of proposed § 422.116(f)(3). This will ensure MA organizations that have received the exception do not submit additional PBPs that are not FI–SNPs to their FI–SNP only contracts. CMS reviews

networks at the contract level which means if an MA organization were to add an MA plan (that is, a PBP) that is not a FI–SNP to a contract, the exception we proposed here will not be appropriate. We asked for comment on this aspect of our proposal and whether additional guardrails are necessary to ensure that the proposed new exception from network adequacy evaluations is limited to FI–SNPs consistent with our rationale for it.

Under our proposal, FI–SNPs will still be required to adhere to § 422.112 regarding access to covered benefits. For example, § 422.112(a)(1)(iii) requires an MA coordinated care plan to arrange for and cover 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. Because all SNPs, including FI–SNPs, are coordinated care plans, this beneficiary protection applies to them. Similarly, the timeliness of access to care requirements newly adopted at § 422.112(a)(6)(i) will apply. We believe that our proposal, as specified in the proposed rule, appropriately balanced the need to ensure access to covered benefits for enrollees in FI–SNPs while recognizing the unique way this type of MA plan furnishes benefits and how enrollees generally receive services at the institution where the enrollee resides. Expanding this proposed new exception from the § 422.116 network adequacy requirements to other I–SNPs that enroll special needs individuals that reside in the community or other SNPs or MA plans that are not designed to furnish services to institutionalized special needs individuals will not be appropriate or serve the best interests of the Medicare program or Medicare beneficiaries.

Summaries of the comments we received on this proposal to amend § 422.116(f) and our responses to them follow.

Comment: Commenters overall were supportive of our efforts to broaden the bases of acceptable rationales for requesting an exception from the requirements in § 422.116 for facility-based I–SNPs. Commenters also expressed support for CMS strengthening its general oversight of I–SNPs to ensure people are receiving the care they need. Specifically, commenters supported the proposal's expanded access to telehealth care to ease beneficiary access to care. Also, commenters believe this proposal is well-positioned to ensure individuals receive necessary supports across the continuum of their care needs without having to experience the disruption of changing Medicare coverage types should there be a need for more extensive long-term care.

Response: CMS appreciates the support for our proposal, which we are finalizing, to establish two new exceptions from the network adequacy evaluations under § 422.116(b) through (e) for certain FI–SNPs, the factors and evidence CMS will consider in whether to grant the exceptions, and the new requirement that an MA organization that receives an exception for its FI–SNP(s) only offer FI–SNPs under the contract that receives the exception approval. CMS would like to thank all the commenters for their comments.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing the revisions to § 422.116(f) as proposed.

F. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

Dually eligible individuals face a complex range of enrollment options based on MA plan types (that is, HMOs, PPOs, private fee-for-service plans, MA special needs plans, etc.), enrollment eligibility, and plan performance, but which do not consider the enrollee's Medicaid choice. Further, many of the coverage options available to dually eligible individuals—even including many dual eligible special needs plans (D–SNP)—do not meaningfully integrate Medicare and Medicaid, chiefly because the parent organization of the D–SNP does not also provide the enrollee's Medicaid services. The current managed care enrollment and eligibility policies have resulted in a proliferation of such D–SNPs and leave dually eligible individuals susceptible to aggressive marketing tactics from agents and brokers throughout the year.

Over the last decade, we have taken numerous steps to improve the experiences and outcomes for dually eligible individuals through various forms of Medicare-Medicaid integrated care. Despite progress, there remain a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment [209]). In the final rule titled Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid fee-for-service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS–4185–F) (hereinafter referred to as the April 2019 final rule), we expressed our belief that aligned enrollment, and especially exclusively aligned enrollment (when enrollment in a parent organization's D–SNP is limited to individuals with aligned enrollment), is a critical part of improving experiences and outcomes for dually eligible individuals.

Longer term, for dually eligible individuals who are in Medicare and Medicaid managed care, we believe that we should continue to drive toward increasing aligned enrollment until it is the normative, if not only, managed care enrollment scenario. Our proposals represented an incremental step toward increasing aligned enrollment, balancing our long-term policy vision with our interest in limiting disruption in the short term. For dually eligible individuals that elect MA plans, we are focused on increasing enrollment in integrated D–SNPs: fully integrated dual eligible special needs plans (FIDE SNPs),[210] highly integrated dual eligible special needs plans (HIDE SNPs),[211] and applicable integrated plans (AIPs).[212] These D–SNP types more meaningfully integrate Medicare and Medicaid services and administrative processes (such as unified appeals and grievances) than coordination-only D–SNPs [213] that are not also AIPs.

[209] 42 CFR 422.2 (definition of ''aligned enrollment'').

[210] Effective 2025, FIDE SNPs as defined in § 422.2 are required to have EAE and would therefore be AIPs by definition. To receive the FIDE designation, a D–SNP would be required to provide nearly all Medicaid services, including long-term services and supports, Medicaid behavioral health services, home health and DME.

[211] HIDE SNPs as defined in § 422.2 are required to cover long-term services and supports or behavioral health services but may have more Medicaid services carved out relative to plans with the FIDE designation. HIDE SNPs that also operate with EAE would meet the definition of an AIP, but there is no requirement for EAE for the HIDE designation.

[212] AIPs as defined in § 422.561 are D–SNPs with EAE, where the companion Medicaid MCO covers Medicaid benefits including primary care and acute care, Medicare cost-sharing, and at a minimum one of the following: home health services, medical supplies, equipment, and appliances (DME), or nursing facility services.

[213] Dual eligible special needs plans (D–SNPs) are defined at § 422.2. ''Coordination-only'' D–SNPs are D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and for which there are no Federal requirements to cover any Medicaid

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In the November 2023 proposed rule, we described interconnected proposals that would (1) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP, (2) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis, (3) limit enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (4) limit the number of D–SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO in order to reduce ''choice overload'' of D–SNP options in certain markets. Affiliated Medicaid MCOs are Medicaid MCOs offered by the MA organization, the same parent organization, or another subsidiary of the parent organization. We noted that, in combination, our proposals would create more opportunities for dually eligible individuals to elect integrated D–SNPs, more opportunities to switch to Traditional Medicare, and fewer opportunities to enroll in MA–PD plans that do not integrate Medicare and Medicaid services. Table HC1 summarizes the combined effects of these proposals, then we describe each proposal in greater detail.

Table HF1: Enrollment scenarios under current rules and proposed amendment—individual perspective *(Note - table does not include other applicable SEPs)*

Scenarios for dually eligible individuals	Current rules under quarterly dual/LIS SEP	Proposed monthly dual/LIS SEP, integrated care SEP, and enrollment limitations for non-integrated MA-PD plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable[214]
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month, but must be aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	**Current rules**	**As proposed**
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

We proposed to create a new SEP and revise the dual/LIS SEP but otherwise did not change the remaining SEPs. To highlight the changes in our proposals without overly complicating this table, we did not reference the other SEPs.

benefits either directly or through an affiliated Medicaid managed care plan.

[214] We proposed that during AEP and other available enrollment periods, MA organizations would not be permitted to enroll dually eligible individuals into a D–SNP where such enrollment would not result in aligned enrollment with an affiliated Medicaid MCO offered in the same service area (that is, a Medicaid MCO offered by the MA organization, its parent organization, or another subsidiary of the parent organization).

1. Proposed Changes to the Special Enrollment Periods for Dually Eligible Individuals and Other LIS Eligible Individuals

Section 1860D–1(b)(3)(D) of the Act directs the Secretary to establish an SEP for full-benefit dually eligible individuals under Part D. The SEP, subsequently referred to as the continuous dual/LIS SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation. The continuous dual/LIS SEP allowed eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA–PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the AEP or via other applicable SEPs each year.

In the April 2018 final rule, we cited concerns with usage of the continuous dual/LIS SEP related to enrollees changing plans frequently, hindering care coordination efforts by D–SNPs; plans having less incentive to innovate and invest in serving high-cost enrollees who may disenroll at any time; and agents and brokers targeting dually eligible individuals due to their ability to make enrollment elections throughout the year (83 FR 16514). Ultimately, the April 2018 final rule amended the continuous dual/LIS SEP to allow usage once per calendar quarter during the first nine months of the year (that is, one election during each of the following time periods: January–March, April–June, July–September).

The quarterly dual/LIS SEP reduced individuals moving from one Part D plan (including an MA–PD) to another Part D plan (including an MA–PD) as frequently. However, in the November 2023 proposed rule we discussed the ongoing concerns with the quarterly dual/LIS SEP:

- *Marketing.* We remain concerned about marketing opportunities, especially when they focus on dually eligible individuals who, as a group, have lower levels of education, health literacy, and access to resources that could help overcome sub-optimal coverage decisions. Because the quarterly dual/LIS SEP still allows the vast majority of dually eligible individuals to enroll in almost any MA–PD plan, they remain a target for marketing activities from all types of plans throughout the year.
- *Ability to enroll in integrated D–SNPs.* The quarterly dual/LIS SEP does not allow dually eligible individuals to enroll in integrated D–SNPs after those individuals have exhausted the opportunities allowed by the quarterly dual/LIS SEP.
- *Complexity for States.* The quarterly dual/LIS SEP has created some challenges related to aligning Medicare and Medicaid enrollment dates for dually eligible individuals seeking to enroll in integrated products. In the capitated financial alignment models of the Financial Alignment Initiative (FAI), we waived the quarterly dual/LIS SEP rules at State request to allow for monthly opportunities for individuals to enroll or disenroll. This alleviated the complexity of different Medicare and Medicaid enrollment periods and allows dually eligible individuals more opportunities to enroll in integrated products.
- *Complexity for enrollment counselors and individuals.* Enrollment counselors such as State Health Insurance Assistance Programs (SHIPs) and State ombudsman programs have also noted that the once-per-quarter rule is complicated and makes it difficult to determine the enrollment options available to dually eligible individuals.

To further protect Medicare beneficiaries, reduce complexity for States and enrollment counselors, and increasingly promote integrated care, we proposed two SEP changes. Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish SEPs for full-benefit dually eligible individuals, although it does not specify the frequency or mechanics of those SEPs. Further, section 1860D–1(b)(3)(C) of the Act grants the Secretary the authority to create SEPs for individuals who meet other exceptional circumstances.[215] Section 1859(f)(1) of the Act permits the Secretary to set forth regulations related to how MA organizations restrict the enrollment of individuals who are within one or more classes of special needs individuals. Section 1859(f)(6) establishes the authority to adopt a transition process to move dually eligible individuals out of SNPs when they are not eligible for the SNP. Section 1859(f)(8) of the Act also reflects an interest in and goal of furthering the integration of D–SNPs; the requirement for us to establish procedures for unified grievance and appeals processes and requirement, in section 1859(f)(8)(D), for a mandatory minimum level of integration illustrate how efforts to increase integration in implementing and adopting standards for the MA program further the goals of the program. Based on this, as outlined in detail in the November 2023 proposed rule (88 FR 78568 through 78569), we proposed to amend § 423.38(c)(4)(i) to replace the quarterly dual/LIS SEP with a simpler new dual/LIS SEP. The proposed dual/LIS SEP would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan.

We noted that, functionally, the proposed revised dual/LIS SEP would mean that such individuals could, in any month, switch PDPs or leave their MA–PD for Traditional Medicare plus a standalone PDP (plans that only offer prescription drug coverage). However, as proposed, the dual/LIS SEP would no longer permit enrollment into MA–PD plans or changes between MA–PD plans, although such options would still be available where another election period permits.

In conjunction, based on the statutory authorities described above, we also proposed to create a new integrated care SEP at § 423.38(c)(35) for dually eligible individuals. This new integrated care SEP would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans.

For dually eligible individuals, our two SEP proposals would allow a *monthly* election to:

- Leave an MA–PD plan for Traditional Medicare by enrolling in a standalone PDP,
- Switch between standalone PDPs, or
- Enroll in an integrated D–SNP such as a FIDE, HIDE, or AIP.

If an eligible individual attempts to use, or uses, both the monthly dual/LIS SEP and the integrated care SEP within the same month, the application date of whichever SEP is elected last in time is the SEP effectuated the first of the following month.

As a result of these proposals, dually eligible and other LIS-eligible individuals, like other Medicare beneficiaries, would be able to enroll into non-AIP coordination-only D–SNPs[216] or other MA plans only during the ICEP, AEP, or where another SEP permits. While the proposed changes constrain some enrollment options at certain times of the year, dually eligible individuals and other LIS-eligible individuals would never have fewer choices than people who are not dually or LIS eligible.

In the November 2023 proposed rule we stated our belief that the proposed SEP changes would create more opportunity for dually eligible or LIS individuals to leave MA–PD plans if

[216] Dual eligible special needs plans (D–SNPs) are defined at § 422.2. ''Coordination-only'' D–SNPs are D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and are not required to cover any Medicaid benefits.

MA is not working well for them; reduce the incentive for most plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of the AEP; increase transparency for Medicare beneficiaries and enrollment counselors; create more opportunities for enrollment into integrated D–SNPs; reduce the burden on States working to align Medicaid MCO and D–SNP enrollment; and strengthen incentives for MA sponsors to also compete for Medicaid managed care contracts.

We also noted some potential challenges of our proposal, including limiting dually eligible individuals' ability to change MA–PD plans outside of the AEP, MA–OEP, or other available SEPs in States with few or no integrated D–SNPs; less incentive for MA plans to innovate and invest in meeting the needs of high-cost dually eligible enrollees because such individuals can disenroll at any time; and dually eligible individuals changing between integrated care plans monthly, potentially hindering care coordination and case management efforts. In addition, since LIS individuals without Medicaid are ineligible for integrated D–SNPs, our proposal limits how the dual/LIS SEP can be used for these individuals compared to the current scope of the SEP.

Section 423.40(c) currently provides that the effective date of an enrollment change in Part D during a special enrollment period specified in § 423.38(c), including the existing SEP for dually eligible and other LIS-eligible individuals, will be the first day of the calendar month following the month in which the election is made, unless otherwise noted. In the November 2023 proposed rule, we requested comments on using flexibilities at section 1851(f)(4) of the Act and at § 423.38(c) to establish a Medicare enrollment effective date for the integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP to better align with Medicaid managed care enrollment cut-off dates, as some States do not enroll individuals on the first of the month following an enrollment request after a certain cut-off date and delay the effective date until the first of the following month.

2. Enrollment Limitations for Non-Integrated Medicare Advantage Plans

Aligned enrollment is a key feature of the FAI, PACE, and other long-standing integrated care programs such as the Massachusetts' Senior Care Options and Minnesota's Senior Health Options that started as demonstration programs that were precursors to D–SNPs. Individual States may also use their State Medicaid agency contracts (SMAC) to limit enrollment in a D–SNP to the enrollees in an affiliated Medicaid MCO. Further, we have adopted, as part of the definition in § 422.2, enrollment limits for FIDE SNPs that require, beginning January 1, 2025, FIDE SNPs to have exclusively aligned enrollment.

Separate from contracting with D–SNPs via SMACs, States have discretion in how they arrange their Medicaid managed care programs and may use Medicaid MCOs to cover a comprehensive scope of Medicaid benefits or use prepaid health plans to cover a smaller scope of Medicaid benefits.[217] Many States with Medicaid managed care programs select a limited number of Medicaid MCOs through a competitive procurement process.

In many service areas, dually eligible individuals face complicated enrollment policies, overwhelming marketing, and an increasingly complex array of plans purportedly designed especially for them but that do not offer meaningful Medicare and Medicaid integration due to service area and enrollment misalignment.

We noted in the November 2023 proposed rule that some States have utilized SMACs and selective contracting to limit the availability of D–SNPs in the State to those MA organizations that also have contracts with the State to cover Medicaid services. However, other D–SNP markets have grown without any limitations on non-integrated plans. In some markets, parent organizations of MA organizations have acquired multiple D–SNPs by purchasing smaller plans and have not consolidated the various plans, resulting in one parent organization operating multiple D–SNPs within a single State, often with overlapping service areas. For States that do not require parent organizations to consolidate their plans, multiple D–SNPs of this type may continue to operate indefinitely. This creates a market with a large number D–SNP options that often do not offer significantly different benefits or networks, which creates confusion for plan selection and could lead to individuals choosing unaligned Medicare and Medicaid plans.

We recognize that States have policy interests and goals that shape their Medicaid managed care programs, and our intent is to help further support States interested in implementing EAE. We have historically deferred to States to use SMACs to align Medicare and Medicaid plan offerings consistent with State policy priorities. However, as the number of dually eligible individuals with misaligned enrollment and sheer number of D–SNPs have grown, we noted in the November 2023 proposed rule that we now believe that Federal rulemaking is warranted to promote greater alignment of D–SNPs and Medicaid MCOs and to begin to simplify the array of choices.

We have authority, per section 1857(e)(1) of the Act, to add MA contract terms and conditions not inconsistent with the MA statute (that is, Part C of Title XVIII of the Act) as the Secretary may find necessary and appropriate. Given how section 1859(f)(8) of the Act reflects a goal of furthering the integration of D–SNPs and how our proposal is designed to reduce choice overload situations for dually eligible individuals while furthering opportunities for enrollment in integrated D–SNPs (that is, FIDE SNPs, HIDE SNPs, and AIPs), we believe that the standard in section 1857(e)(1) is met. Further, section 1854(a)(5) of the Act is clear that we are not obligated to accept any and every MA plan bid. Based on this, we proposed new regulations §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii).

At § 422.503(b)(8), we proposed to establish a new qualification for an MA organization (or new applicant to be an MA organization) to offer D–SNP(s) while at § 422.504(a)(20) we proposed to establish a new contract term for certain MA organizations. At § 422.514(h), we proposed to establish conditions for how certain MA organizations and D–SNPs may enroll dually eligible individuals and limit the number of D–SNPs that may be offered by certain MA organizations. Finally, at § 422.530(c)(4)(iii), we proposed to establish a new crosswalk exception to authorize MA organizations that are subject to these new enrollment limitations to crosswalk their enrollees to a single D–SNP to accomplish aligned enrollment.

Together, our proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) would require the following:

- Beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls dually eligible individuals in the same service area, D–SNPs offered by the MA organization, its parent organization, or

[217] See 42 CFR 438.2 for definitions of the terms managed care organization (MCO), prepaid ambulatory health plan, and prepaid inpatient health plan.

an entity that shares a parent organization with the MA organization, must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D–SNP's affiliated Medicaid MCO. This would apply when any part of the D–SNP service area(s) overlaps with any part of the Medicaid MCO service area, even if the two service areas do not perfectly align. Additionally, only one D–SNP may be offered by an MA organization, its parent organization, or another MA organization with the same parent organization in the same service area as the aligned Medicaid MCO. We would only enter into a contract with one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO (with limited exceptions as described below).

- Beginning in 2030, such D–SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO. Therefore, by 2030, integrated D–SNPs would be required to disenroll individuals who are not enrolled in both the D–SNP and Medicaid MCO offered under the same parent organization (that is, offered by the parent organization or any subsidiary), except that D–SNPs would still be able to use a period of deemed continued eligibility to retain enrollees who temporarily lost Medicaid coverage as described in § 422.52(d). This also means that where an enrollee is temporarily disenrolled from the affiliated Medicaid MCO but is expected to be re-enrolled in the affiliated Medicaid MCO within the period of deemed continued eligibility, the D–SNP would not be required to disenroll that enrollee during that period.

Consistent with how we believe MA organizations under the same parent organization share operational and administrative functions, we proposed to apply the regulations at the parent organization level.

To minimize enrollment disruption associated with achieving compliance with our other proposals, we proposed a corresponding new provision at § 422.530(c)(4)(iii) that would provide a new crosswalk [218] exception to allow one or more MA organizations that share a parent organization and offer D–SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D–SNPs to comply with the new rules in proposed §§ 422.504(a)(20) and 422.514(h). The proposed new crosswalk exception would explicitly permit moving enrollments across contracts held by MA organizations with the same parent organization; because we are not including any explicit exception from the rule in § 422.530(a)(2) prohibiting crosswalks to different plan types, the receiving D–SNP must be the same plan type as the D–SNP out of which the enrollees are crosswalked. We noted our expectation that MA organizations who offer D–SNPs would leverage § 422.530(c)(4)(iii)—as well as standard MA processes to add or remove service areas—to come into compliance with § 422.514(h).

In addition, we proposed to codify at § 422.514(h)(3) two exceptions to our new proposed requirements at § 422.514(h)(1) and (2) (the exceptions would carry over as part of the cross-references to compliance with § 422.514(h) in §§ 422.503(b)(8), 422.504(a)(20), and 422.530(c)(4)(iii)). In certain circumstances, State D–SNP policy may require the need for more than one D–SNP for full-benefit dually eligible individuals to operate in the same service area. Under § 422.514(h)(3)(i), we proposed to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, offering more than one D–SNP for full-benefit dually eligible individuals in the same service area. For example, where a SMAC limits enrollment for certain groups into certain D–SNPs (such as by age group), the MA organization may offer additional D–SNPs for different groups of full-benefit dually eligible individuals in the same service area accordingly. As proposed, the exception would only be available where the SMAC requires different eligibility groups for the different D–SNPs that are offered by the same MA organization, its parent organization, or another MA organization that shares the parent organization; this proposed exception would allow States the flexibility to design future integrated D–SNP programs with eligibility nuances should they so choose.

To minimize enrollee disruption, our second proposed exception would not prohibit an MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization, from continuing to operate both an HMO D–SNP and a PPO D–SNP in a State where the proposed new policy applies. To achieve the goals of the new regulation, including simplification of the D–SNP market and promotion of integrated care through aligned Medicare and Medicaid products, we proposed at § 422.514(h)(3)(ii) that the MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may offer (or continue to offer) both the HMO and PPO D–SNPs only if they no longer accept new full-benefit dually eligible enrollees in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). Under this proposal, the MA organization, its parent organization, and another MA organization that shares a parent organization with the MA organization may only accept new enrollment in one D–SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and such new enrollment is limited to the full-benefit dually eligible individuals who are enrolled (or are enrolling) in the affiliated Medicaid MCO.

We also proposed at § 422.503(b)(8) that in service areas in which a D–SNP limits enrollment to individuals enrolled in (or in the process of enrolling in) an affiliated Medicaid MCO, the MA organization, its parent organization, or entities that share a parent organization with the MA organization may not newly offer another D–SNP for full-benefit dually eligible individuals, if it would result in noncompliance with § 422.514(h). Additionally, we proposed at § 422.504(a)(20) to establish a new contract term for MA organizations that offer D–SNPs to require compliance with the enrollment limits we are proposing to add to § 422.514(h).

Table HC2 summarizes enrollment scenarios to illustrate the combined effects of our proposed SEP changes and enrollment limitations. The term ''D–SNP's parent organization'' as used in the table includes the MA organization that offers the D–SNP, the MA organization's parent organization, and any other entity (MA organization or otherwise) that shares the parent organization with the MA organization that offers the D–SNP.

[218] A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollee from one PBP to another is to change the enrollment from the first PBP to the second.

Table HF2: 2027 Scenarios for D-SNP enrollment under the proposed integrated care SEP and proposed enrollment limitations – plan perspective

Scenario	Who can enroll in the D-SNP?	When can such individuals enroll in the D-SNP?
D-SNP's parent organization has an affiliated Medicaid MCO that enrolls full-benefit dually eligible individuals in same service area	Only enrollees in the parent organization's companion Medicaid MCO who also meet eligibility requirements based on terms of that State's SMAC	Each month
D-SNP's parent organization does NOT have an affiliated Medicaid MCO that enrolls full-benefit dually eligible individuals in same service area	Any individuals who meet eligibility requirements based on terms of that State's SMAC	Only during ICEP, AEP, MA-OEP, or via an existing SEP

We noted that our proposals on enrollment limitations for non-integrated D–SNPs would apply based on an MA organization having an affiliated Medicaid MCO. However, we noted that we considered whether our proposals should apply where an MA organization has other affiliated Medicaid managed care plan options as well, including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). We expressed concern that applying our proposals to PIHPs and PAHPs could cause disruption without significantly furthering the goals of our proposals, but we solicited comments on the issue.

We noted that our proposals would require updates to the systems and supports designed to aid individuals in making Medicare choices. This includes MPF, HPMS, and other resources that help to outline available plan choices and is important where dually eligible individuals have choices that would vary based on the type of plan and time of year. We noted that we would welcome recommendations on how the choice architecture could best support the proposals or objectives described in the November 2023 proposed rule.

Overall, we noted our proposals at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii) would increase the percentage of D–SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment (EAE), increasing access to the comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D–SNPs; prompt MA organizations to consolidate PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps the D–SNPs service area; reduce the number of D–SNP options and reduce choice overload and market complexity where parent organizations offer multiple D–SNP options in the same or overlapping service areas; remove some incentives for agents and brokers to target dually eligible individuals lessening the assistance needed from advocates and SHIP counselors to correct enrollment issues; and simplify provider billing and lower the risk of inappropriate billing.

While noting many benefits to our proposals, we acknowledged certain challenges:

- Our proposals would reduce the number of D–SNP options for Medicaid MCO enrollees in some States. It is plausible that some dually eligible individuals could benefit from the unique combinations of provider networks and supplemental benefits that could be possible only by enrolling in misaligned Medicare and Medicaid plans.
- Making plan choices clear under our proposals to dually eligible individuals, SHIP counselors and others would require changes to MPF, HPMS, and other CMS public materials explaining Medicare coverage options. Systems changes often present unknown challenges and a learning curve for users while they become accustomed to new updates.
- It also may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals would have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new one-time-per month SEP. Therefore, we believe our proposals, in combination, would maintain a high level of competition and choice, even while imposing some new constraints.
- MA organizations that operate both D–SNPs and Medicaid MCOs might elect to participate in fewer competitive Medicaid procurements (or exit Medicaid managed care in ''any willing provider'' States) to be exempted from the proposed restrictions on plan enrollment and number of plan offerings. This could adversely affect competition and the minimum choice requirements in § 438.52 for Medicaid managed care programs. However, our SEP proposals would have the opposite effect, since only integrated D–SNPs could benefit from the new integrated care SEP, and overall, we believe our proposals, in combination, maintain strong incentives for organizations to compete for Medicaid managed care contracts.
- The enrollment and eligibility restrictions—without the offsetting proposed SEP changes—could incentivize sponsors to create D–SNP look-alikes or other types of MA plans

to build enrollment of dually eligible individuals without being subject to the enrollment limits and integration requirements associated with D–SNPs (although we plan to mitigate this risk with proposed revisions to § 422.514(d) and (e) in section VIII.G of the proposed rule). Finally, beginning in 2030, our proposal would no longer allow some enrollees to stay in their current D–SNPs, causing some enrollee disruption where the D–SNPs were unable to completely align their D–SNP and Medicaid MCO populations.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters, including MedPAC and MACPAC, generally supported the proposals to increase the percentage of dually eligible individuals who receive Medicare and Medicaid services from the same organization. These commenters noted the proposals, taken together, would reduce administrative burden, support Medicaid agencies' ability to coordinate care, create more efficient program management, make it easier to navigate integrated care, and strengthen integrated care plans so that Medicare and Medicaid feel like one program. Some commenters stated the proposals would help to address marketing practices by MA organizations and agents and brokers that can be overwhelming and misleading, contributing to coverage decisions that do not meet enrollees' needs. A few commenters stated that the proposed changes may result in short-term disruptions to care but, in the long term, would significantly increase the percentage of dually eligible individuals receiving integrated care, which would likely result in improved care coordination, access to services, health outcomes, and enrollee experience. A commenter expressed support for the proposals, citing expanded access to integrated materials unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. A commenter also stated the proposals would improve the health care and social service needs of dually eligible individuals through the delivery of care and services that are coordinated through aligned enrollment in integrated Medicare and Medicaid plans. A commenter supported the proposal and noted navigating separate programs makes it extremely difficult for health care providers to deliver patient-centered care and challenging for individuals and their families to navigate care, appeal a coverage decision, or determine who to call for help.

Response: We appreciate the comments and support for increasing the percentage of dually eligible individuals in aligned enrollment. We agree with commenters that the proposal would reduce the volume of marketing activities, improve integration of Medicare and Medicaid services, and simplify navigation of complex programs for enrollees, their caregivers, and other groups supporting dually eligible individuals.

Comment: Many other commenters generally opposed the interconnected SEP and enrollment limitation proposals. A number of commenters stated they understand—and in some cases support—CMS's goal to improve integrated care for dually eligible individuals but believe CMS's proposals would lead to unintended consequences and overly burdensome requirements that could ultimately lead to fewer plans in some service areas, reducing MA plan competition and beneficiary choice. Some commenters stated the proposals would increase burden and complexity for States. Some commenters recommended CMS consider and mitigate any negative impacts on access prior to adopting policies that would limit the number of D–SNPs offered by MA organizations. A commenter also expressed general concern with the proposals and urged CMS to not move forward with finalizing the proposed changes.

Response: We acknowledge the commenters' perspectives on the proposals. As noted in the proposed rule (88 FR 78567), we believe our proposals represent an incremental step toward increasing aligned enrollment for dually eligible individuals who are in Medicare and Medicaid managed care, balancing our long-term policy vision with our interest in limiting disruption in the short term. We believe the combination of the SEP and enrollment limitation policies maintain strong incentives for organizations to compete for Medicaid managed care contracts while also reducing choice overload and incentives for agents and brokers that target dually eligible individuals. Further, we believe the opportunity to increase access to comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials outweighs any disadvantages in the shorter term.

Comment: Numerous commenters, including MedPAC and MACPAC, supported the proposals that would (1) replace the quarterly dual/LIS SEP with a monthly dual/LIS SEP that allows individuals enroll in Traditional Medicare and a PDP, and (2) create the new monthly integrated care SEP. A number of commenters stated the changes to the dual/LIS SEP would reduce aggressive marketing tactics from agents and brokers targeting dually eligible individuals and simplify counseling and messaging for the monthly SEP. Some commenters noted the SEPs give individuals freedom of choice because they are not locked into a plan for months that does not work for them. Other commenters stated the SEPs create less complexity for Medicaid agencies to navigate since the quarterly SEP posed challenges in aligning Medicare and Medicaid enrollment. A number of commenters noted the integrated care SEP would give enrollees the ability to enroll monthly into an integrated plan to access needed services and address complex chronic care needs. Some commenters stated only allowing movement into integrated plans would lessen agents' and brokers' ability to enroll dually eligible individuals into coordination-only D–SNPs that create fragmentation and disintegration.

Response: We thank the commenters for their support of the SEP-related proposals. We agree these changes will help to address aggressive marketing, simplify messaging for dually eligible individuals and choice counselors, reduce complexity for States, and overall increase the percentage of dually eligible managed care enrollees who are in FIDE SNPs, HIDE SNPs, and AIPs. We continue to believe that aligned enrollment, and especially exclusively aligned enrollment, is a critical part of improving experiences and outcomes for dually eligible individuals and will continue to drive toward increasing aligned enrollment until it is the normative, if not only, managed care enrollment scenario.

Comment: A number of commenters expressed concerns about the impact of the SEP proposals on partial-benefit dually eligible individuals and noted that partial-benefit dually eligible individuals would not be able to benefit from the integrated care SEP. Several commenters stated that partial-benefit dually eligible individuals experience similar health care needs as full-benefit dually eligible individuals and should have access to the same enrollment opportunities using SEPs. A commenter stated that partial-benefit dually eligible individuals may have greater health care needs since their health may worsen over time due to lack of State coverage and payment for necessary services and should have access to the same plan options.

A number of commenters indicated that partial-benefit dually eligible enrollees in MA plans and D–SNPs benefit from lower cost sharing, greater coordination of care and services, and access to supplemental benefits that are not available in the Traditional Medicare environment, plus disease management for those with chronic illnesses. A few of these commenters stated that although these enrollees do not have access to and thus do not require coordination of Medicaid services, they can nevertheless benefit from the model of care provided by coordination-only D–SNP plans, which are not present in traditional MA–PD plans or Traditional Medicare. Another commenter requested that CMS reconsider how CMS's SEP proposals may result in greater dislocation, reduced care management, increased marketing, and reduced opportunities for partial-benefit dually eligible and LIS individuals.

Some commenters urged CMS to either retain the quarterly dual/LIS SEP or create a corresponding SEP allowing partial-benefit dually eligible individuals to enroll in coordination-only D–SNPs. A commenter noted that a quarterly SEP for coordination-only D–SNP enrollment would ensure equity and parity between partial-benefit and full-benefit dually eligible individuals.

A few commenters expressed concern about the impact of CMS's SEP proposal on dually eligible individuals who are not Qualified Medicare Beneficiaries (QMBs). The commenter noted that if these individuals needed to change coverage outside of the standard enrollment periods, due to the lack of comprehensive Federal Medigap protections, they may not be eligible for a Medigap plan. Even if they were able to enroll, most Medigap plans have unaffordable premiums or out-of-pocket costs making enrollment in Traditional Medicare unattractive.

Response: We thank the commenters for their perspectives. We noted in the proposed rule (88 FR 78570) that our proposals at § 423.38(c)(4)(i) would allow partial-benefit dually eligible individuals and LIS eligible individuals the opportunity to disenroll from an MA–PD plan (to Traditional Medicare) in any month throughout the year and switch between standalone PDPs on a monthly basis. CMS regulations do not prohibit partial-benefit dually eligible individuals from enrolling in non-AIP HIDE SNPs; however, States may require more limited enrollment in HIDE SNPs via the SMAC.

We acknowledge the SEP proposals limit opportunities for partial-benefit dually eligible individuals and LIS eligible individuals to enroll in MA–PDs and coordination-only D–SNPs. Partial-benefit dually eligible individuals and LIS eligible individuals would still have the ability to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits.

With regard to retaining the quarterly dual/LIS SEP or creating a new SEP for partial-benefit dually eligible individuals to enroll in coordination-only D–SNPs, we direct the commenter's attention to the proposed rule (88 FR 78571), where we expressed our belief that the current managed care enrollment and eligibility policies have resulted in a proliferation of coordination-only D–SNPs and leave dually eligible individuals susceptible to aggressive marketing tactics from agents and brokers throughout the year. Adopting a new SEP for partial-benefit dually eligible individuals or extending the new integrated care SEP that we are adopting at § 423.38(c)(35) would not address that concern and would not further our goals of increasing aligned enrollment in integrated D–SNPs.

We recognize that non-QMB dually eligible individuals who enroll in Traditional Medicare may not be able to select a Medigap plan to cover cost-sharing, depending on the timing of that choice and State laws regarding Medigap enrollment. However, this is also true today, and we believe the benefits of the SEP proposals, including protecting Medicare enrollees from aggressive marketing tactics, reducing complexity for States and enrollment counselors, and promoting access to integrated care, outweigh the potential drawbacks.

Comment: Several commenters believed the integrated care SEP would only allow for enrollment in AIPs. A few commenters raised concerns about the potential for continued enrollment in misaligned plans. A commenter identified a State that is implementing default enrollment to increase alignment between Medicaid and Medicare but does not require HIDE SNPs to operate with exclusively aligned enrollment (EAE). The commenter further stated that the integrated care SEP would undermine current enrollment alignment, citing that it does not take into account Medicaid MCO enrollment and would give dually eligible individuals more opportunities to misalign their Medicare and Medicaid coverages. Another commenter urged CMS to consider a bar on new enrollments without concurrent alignment. The commenter recommended limiting the use of the integrated care SEP only when it would result in aligned enrollment with the Medicaid MCO.

Response: We share the concerns raised by commenters that, in certain instances, dually eligible individuals already enrolled in aligned plans could use the integrated care SEP as originally proposed at § 423.38(c)(35) to misalign their Medicare and Medicaid coverage. In States that do not require EAE, default enrollment mechanisms authorized under § 422.66(c)(2) can be used to enroll dually eligible individuals in a D–SNP that is affiliated with the Medicaid MCO in which the individual is enrolled for Medicaid coverage. However, without a State requiring D–SNPs to comply with EAE requirement as part of their SMAC, dually eligible individuals would theoretically be able to use the proposed integrated care SEP to elect a non-aligned HIDE SNP.

In the proposed rule (88 FR 78567), we discussed the primary goals of the proposals to drive toward increasing aligned enrollment for dually eligible individuals who are in Medicare and Medicaid managed care. The SEP polices we proposed and are finalizing are intended to create more opportunities for enrollment in integrated D–SNPs so that dually eligible individuals can experience plans that more meaningfully integrate Medicare and Medicaid services. While the integrated care SEP, as proposed, would create more opportunities to elect integrated D–SNPs, it could potentially also allow opportunities to misalign enrollment to persist in limited situations, which is contrary to our policy goals or intent for this new SEP.

After considering the comments received, we are finalizing the integrated care SEP with a narrower scope so that dually eligible individuals may use the SEP to enroll in a FIDE SNP, HIDE SNP, or AIP if they are enrolled in or in the process of enrolling in the sponsor's affiliated Medicaid managed care plan. We are finalizing § 423.38(c)(35) largely as proposed but with a modification that the SEP is available only to facilitate aligned enrollment, as that term is defined in § 422.2. As a result of this limitation, this SEP will effectively be limited to full-benefit dually eligible individuals because ''aligned enrollment'' is defined by reference to full-benefit dual eligibility. Adding this limitation to the integrated care SEP creates less opportunity for full-benefit dually eligible individuals to misalign their Medicare and Medicaid plans. Because FIDE SNPs (starting in 2025) and AIPs feature exclusively aligned enrollment, the effect of this change from our

original proposal is specific to HIDE SNPs. Relative to our original proposal, the same range of plans can enroll people using the finalized SEP, but it can be used in fewer circumstances and only by full-benefit dually eligible individuals: the integrated care SEP may be used only when it achieves aligned enrollment.

Comment: A few commenters expressed their belief that a monthly SEP would result in more marketing toward dually eligible individuals and would allow brokers to potentially take advantage of prospective enrollees.

Response: We appreciate the perspective raised by commenters but disagree that the monthly SEP, in combination with our other proposals, would result in more marketing toward dually eligible individuals or would allow brokers to potentially take advantage of prospective enrollees. As we noted in the proposed rule (88 FR 78570), we believe the proposals would remove some incentives both for MA–PD plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of the AEP and for agents and brokers to target dually eligible individuals (especially among employed or captive agents affiliated with plans that do not offer integrated D–SNPs). Based on our review of 2023 plans, approximately 5 percent of the plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the proposed new monthly integrated care SEP at § 423.38(c)(35).

Comment: A few commenters expressed concern that the proposed monthly integrated care SEP could negatively impact an MA organization's Star Ratings, stating that allowing dually eligible individuals to make enrollment decisions on a monthly basis would be disruptive and impact quality outcomes, making it more difficult for plans to maintain or improve Star Ratings. A commenter further stated that where State Medicaid managed care programs require minimum Star Ratings of D–SNPs with affiliated Medicaid MCOs, the monthly integrated care SEP could result in non-compliance with that standard and jeopardize their ability to provide Medicaid coverage. Another commenter suggested that if CMS finalizes the monthly integrated care SEP proposal, CMS should make changes to the *Members Choosing to Leave the Plan* measure to exclude individuals who disenroll under the monthly SEP to move into a plan with a higher level of integration or from one D–SNP type to another, given the enrollment change is driven by something other than dissatisfaction with the plan, similar to the current exclusion for individuals enrolling in an employer group plan. Another commenter suggested that the SEP proposals, if finalized, could result in an increase in complaints by dually eligible individuals due to a lack of understanding of the changes to the SEPs and encouraged CMS to consider updating its practices around the Complaint Tracking Module (CTM) for disenrollments accordingly (see section III.O of the final rule for a discussion on codification of complaints resolution timelines and other requirements related to CTMs).

Response: We appreciate the commenters' perspective on this issue. We do not currently have evidence to suggest allowing full-benefit dually eligible individuals the opportunity to enroll into integrated D–SNPs in any month would negatively impact Star Ratings; in fact, we have reason to believe that the totality of the SEP proposals may actually benefit integrated D–SNPs on Star Ratings, including the *Members Choosing to Leave the Plan* measure. In 2023, a study published in *Health Affairs* noted that nearly one-third of dually eligible individuals in ''D–SNP look-alike plans,'' which the authors defined as MA plans that are marketed toward and primarily enroll dually eligible individuals but are not subject to Federal regulations requiring coordination with Medicaid, were previously enrolled in integrated care programs.[219] Such look-alike plans would no longer be able to accept enrollments from beneficiaries using the dual/LIS SEP at § 423.38(c)(4)(i) with our proposed and finalized changes. The dual/LIS SEP at § 423.38(c)(4)(i) would dramatically reduce the total array of options available outside of the AEP while the integrated care SEP at § 423.38(c)(35) allows enrollment by full-benefit dually eligible individuals into integrated D–SNPs, which together may improve integrated D–SNP performance on measures such as *Members Choosing to Leave the Plan.* Further, in the CY 2025 Advance Notice, we discussed a non-substantive update to that measure to exclude any enrollment into a plan designated as an AIP from the numerator of this measure, which could address the concerns if finalized; under the non-substantive update, CMS would treat a change in enrollment to an AIP from a non-integrated MA plan as an involuntary disenrollment.[220] We are committed to monitoring the impact of these policy changes and to considering necessary changes in the future as appropriate.

Comment: Numerous commenters stated the SEP proposals would increase movement in plans that could undermine care coordination and continuity of care. Some commenters expressed concern that D–SNPs would not be able to set up effective models of care if individuals could switch plans monthly. A few commenters stated changing plans monthly could lead to a delay in care if enrollees have to change providers or ask for new referrals for specialists or medications. A commenter stated that using a monthly SEP could cause disruption for dually eligible individuals if they are already receiving ongoing services such as home health, particularly if the new plan does not have the same provider network. A commenter noted that the SEPs would limit plans' ability to address social determinants of health (SDoH). Another commenter stated allowing individuals to change plans monthly creates less effective medication therapy management (MTM) programs.

Response: We thank commenters for their feedback and agree that coordination of care is an important element of integrated care plans. While we acknowledge changing plans monthly could impact coordination of care, we believe the benefits of reduced agent and broker marketing, improved transparency for enrollment counselors and individuals, and increased access to integration of Medicare and Medicaid benefits and administration outweigh the downsides. In addition, for individuals that are receiving an ongoing course of treatment and make an enrollment change, the April 2023 final rule (88 FR 22206) amended § 422.112(b)(8)(i)(B) to require MA organizations offering coordinated care plans, including D–SNPs, to have prior authorization policies that provide for a minimum 90-day transition period for any ongoing course(s) of treatment even if the course of treatment was for a service that commenced with an out-of-

[219] Ma Y., Frakt A., Roberts, E., Johnston K., Phelan J., and Figueroa J. Rapid Enrollment Growth in 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat to Integrated Care. Health Affairs July 2023 [cited February 2024] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00103.*

[220] Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, p127–128. CMS explained that there are two exceptions to this: (1) If the plan in the old contract is also an Applicable Integrated Plan, then the enrollment is not excluded from the numerator; and (2) Any switch between D–SNPs in Florida is not excluded because all D–SNPs in Florida are directly capitated by the State for Medicaid services and therefore already provide aligned Medicare and Medicaid coverage.

network provider. We do not expect the volume of transitions to increase based on this rulemaking, and noted in the proposed rule (88 FR 78570), that approximately 5 percent of the MA–PD plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the once per month integrated care SEP.

As discussed in the proposed rule (88 FR 78570), we believe the integrated care SEP at § 423.38(c)(35) will create more opportunities for full-benefit dually eligible individuals to enroll in integrated plans, promoting coordination of Medicare and Medicaid services from the same organization. This includes plans addressing enrollees' SDoH needs and ensuring effective MTM programs are in place. In addition, we noted in the proposed rule (88 FR 78570) that the dual/LIS SEP at § 423.38(c)(4)(i) allows dually eligible individuals to disenroll from their MA–PD plan if MA is not working well for them. This would allow individuals to access providers that accept Medicare FFS that may not be in the MA plan's network, including providers that may be able to better address SDoH needs. We also note that dually eligible individuals leaving MA–PDs for Traditional Medicare and a PDP would still have access to an MTM program as this is a requirement of Part D plans at § 423.153(d). We do not anticipate the SEP changes will lead to dually eligible individuals making continuous changes to their enrollment or a major increase in SEP usage overall.

We will continue to monitor dual/LIS SEP usage as it transitions to monthly once again and can revisit in future policy making if issues arise.

Comment: Some commenters recommended the integrated care SEP be limited to allow dually eligible individuals in Traditional Medicare or MA–PDs to enroll in integrated D–SNPs but not permit switching between integrated D–SNPs on a monthly basis. Other commenters suggested allowing monthly enrollment into FIDE SNPs, HIDE SNPs, and AIPs but only allowing disenrollment during the AEP and MA–OEP to reduce changes between plans. A commenter supported the integrated care SEP but was concerned it created opportunities for providers to influence individuals' Medicare enrollment choices and recommended permitting dually eligible individuals to enroll into integrated care plans once per month but not allow disenrollments from an integrated care plan to Traditional Medicare.

Response: We thank commenters for the recommendations. We acknowledge the concern that a monthly SEP can disrupt coordination of care. While we acknowledge that there is a risk that full-benefit dually eligible individuals in integrated care plans could use the new integrated care SEP to switch monthly, we think the likelihood is low and the benefits (reduced marketing, improved transparency, and greater access to integrated care) outweigh potential risks.

We will continue to monitor dual/LIS SEP usage as it transitions to once per month again and can revisit in future policy making if issues arise.

Comment: Several commenters recommended limiting use of the integrated care SEP to only allow enrollment into integrated plans with quality ratings that are equal to or higher than the enrollee's current plan. Another commenter suggested only allowing use of the integrated care SEP to enroll in a FIDE SNP, HIDE SNP, or AIP with a Star Rating of four or greater.

Response: We appreciate the recommendations from commenters regarding the importance of high-quality integrated care plans. While we understand commenters' concerns, we do not currently prevent Medicare beneficiaries from enrolling in plans that do not have a quality rating equal to or higher than their current plan's rating when making new enrollment elections. Star Ratings are important indicators of plan performance, but other factors—such as supplemental benefits or participation of certain providers in-network—may make a 4-Star plan a better option for someone currently in a 4.5-Star plan. We do not intend to impose this limitation on the integrated care SEP.

Individuals wishing to enroll in a plan with 5 Stars will continue to have access to the 5-Star SEP at § 423.38(c)(20).

Comment: Other commenters suggested there may be countervailing incentives between the goal of increased integration and CMS's proposal to allow dually eligible individuals to move from an MA plan to Traditional Medicare and change between standalone Part D plans on a monthly basis. A few of these commenters noted that the proposal contradicts the goal of managing the care of an underserved and needy population. A commenter stated that MA plans, regardless of D–SNP integration status, provide a level of coordination that would be lost if enrollees reverted to Traditional Medicare. A commenter stated that potential changes in benefits, personalized care plans, providers, and care coordinators could lead to greater enrollee confusion, treatment errors, and care transition failures resulting in worsening health outcomes. The commenter stated that the core value proposition of integrated D–SNP coverage is the improved and seamless coordination of their Medicare and Medicaid benefits by a single insurer and believed monthly SEPs would damage the aligned enrollment in integrated plans that CMS is trying to accomplish because changes between plans or to Traditional Medicare undermine coordination of care. Another commenter opined that permitting dually eligible individuals to disenroll from MA plans in any month increases opportunities for adverse selection in Traditional Medicare and favorable selection in MA, especially if individuals are disenrolling from MA when they develop complex health needs. The commenter continued that such selection issues could further distort payments to MA plans and increase overall Medicare spending.

Response: We appreciate the commenters' perspectives on this issue. As we discussed in the proposed rule (88 FR 78567), we believe that aligned enrollment and especially exclusively aligned enrollment is a critical part of improving experiences and outcomes for dually eligible individuals because it allows States and plans to achieve greater levels of integration in the provision and coverage of benefits and plan administration for enrollees. Further, in the longer term, we believe that dually eligible individuals who are in Medicare and Medicaid managed care should receive services through the same organization and therefore our proposed and finalized SEPs are designed to incentivize enrollments into integrated D–SNPs to facilitate aligned enrollment as defined in § 422.2 while maintaining an SEP for LIS-eligible and dually eligible individuals to change their Part D coverage.

We acknowledge that under our proposals dually eligible individuals would have more opportunities to enroll in Traditional Medicare compared to opportunities to change enrollment to non-D–SNP MA–PDs and non-integrated D–SNPs. As we noted in the proposed rule (88 FR 78570), the SEP proposal at § 423.38(c)(4)(i) could mean that MA plans have marginally less incentive to innovate and invest in meeting the needs of high-cost dually eligible enrollees when these enrollees may disenroll at any time, thus exacerbating the phenomenon of higher-cost dually eligible individuals disenrolling from MA. However, we believe the benefits of the SEP proposals

outweigh the potential downsides, and we project in section XI of the final rule that our SEP and enrollment limitation policies will result in over $2 billion in Medicare savings over the ten-year projection period. We will continue to monitor dual/LIS SEP usage and can consider future policy options if issues arise.

Comment: Some commenters expressed concern that the SEP proposals may increase burden on States and plans. Several commenters noted the monthly SEPs would be administratively challenging for State Medicaid agencies to operationalize, putting further strain on States that already have limited capacity and budgetary challenges. Others noted a monthly SEP could lead to increased misalignment between Medicare and Medicaid plans because of monthly SEP usage or differences in enrollment effective dates for Medicare and Medicaid causing States to do extra work to continuously align enrollment into Medicaid managed care plans whenever enrollees change between D–SNPs. A few commenters stated the monthly SEPs could increase administrative costs on MA organizations having to track and manage enrollment that is changing monthly, including issuing ID cards, mailing materials, and the like.

Response: We appreciate the commenters' perspectives on this issue. While commenters stated the monthly SEPs would increase State burden, we noted in the proposed rule (88 FR 78570) our perspective that changing the SEPs to monthly would *reduce* burden on States as they work to align Medicaid MCO enrollment to D–SNP enrollment. We still believe this to be the case, even if it is not currently true for all States. This is particularly important for States transitioning their FAI demonstrations to integrated D–SNPs, all of which operated with monthly opportunities to change enrollment after requesting that CMS waive the quarterly dual/LIS SEP when it was initially established. We will continue to support States in their integration efforts by providing technical assistance, including education and support in implementing provisions of this final rule.

We acknowledge the concerns raised on enrollment effective date challenges and MA organizations having to manage a changing enrollment monthly. However, we do not anticipate the SEP changes, in combination with other policies finalized in this rulemaking, will cause a major increase in SEP usage, because, based on our review of 2023 information, only approximately 5 percent of the MA–PD plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the proposed new monthly integrated care SEP (88 FR 78750). Therefore, we do not believe our finalized changes will worsen existing challenges States and plans face around misaligned Medicare and Medicaid enrollment effective dates.

We will continue to monitor dual/LIS SEP usage and can consider future policy making if issues arise.

Comment: Some commenters raised concerns about the potential for increased provider burden as a result of the SEP proposals. A commenter noted, for example, that there are data lags in providers being notified of changes in payer source and coverage information, and more frequent changes in enrollment could result in delays to access to care for individuals and additional billing challenges for providers. A commenter further stated that frequent changes disrupt continuity of care, leading to administrative challenges like new referrals and authorizations, and an increase in administrative tasks like tracking eligibility and billing adding additional costs to providers. Commenters urged CMS to ensure accurate and timely information is available to providers so operations are not disrupted by frequent insurance changes.

Response: Changes in coverage often come with some administrative challenges for enrollees, providers, and health plans. As proposed, our policies would allow some people to change coverage more times per year than our rules permit today. However, our proposals also limit options for changing coverage in other situations, such that we do not expect an increase in total changes in coverage. Furthermore, one way in which we allow more coverage changes per year—changes among PDPs for people in Traditional Medicare—generally does not trigger any changes in provider networks as they would if they were changes from one MA–PD plan to another. The providers seen by dually eligible individuals and LIS-eligible individuals are likely to be enrolled in Medicare and Medicaid; in the unlikely situation that an individual receives treatment from an MA plan network provider that is not enrolled in Medicare, the ability to transition to another healthcare provider that is enrolled in Medicare is significantly easier than identifying a provider in a different MA plan network. Therefore, we are not persuaded by the argument that the SEP proposals would result in significantly more plan changes leading to increased provider burden. As noted in the proposed rule (88 FR 78750) and in previous responses, a relatively small percentage (approximately 5 percent) of the MA–PD plans would be available as options for dually eligible individuals using the proposed new monthly integrated care SEP. As a result, we do not believe that monthly changes would increase under the new SEPs. We also believe that the SEP proposals in combination with those proposed at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii) would simplify provider billing and lower the risk of inappropriate billing, because more enrollees would be in D–SNPs with aligned enrollment, which generally means that providers would submit one bill to one organization, rather than (a) billing a D–SNP for Medicare covered services and the Medicaid plan (or State) for the Medicare cost sharing amount, or (b) having to determine which plan should be the primary payer for services covered in both programs, such as home health or medical equipment.

Comment: Many commenters were concerned that the new SEP proposals would result in confusion among Medicare beneficiaries and allow agents and brokers to continue using aggressive marketing and sales tactics to push optional or supplemental benefits instead of core coverage and/or incentivize them to sign up as many individuals as possible to increase commissions. Another commenter indicated the proposals would lead to greater choice overload and suboptimal coverage decisions. Another commenter stated that the ability to change plans monthly may generate more confusion as to what coverage is available and what providers they can and cannot see for specialized services. Commenters noted that dually eligible individuals often do not understand that a prior authorization does not move with them if they change carriers.

Response: We acknowledge the concerns raised by these commenters; increasing dually eligible individuals' understanding of available coverage options and limiting the use of aggressive marketing tactics by agents and brokers are among the primary goals of these proposals. However, we do not agree that the SEP proposals would create additional confusion and choice overload relative to the status quo. As we noted in the proposed rule (88 FR 78570), we believe the SEP proposals would reduce the incentive for plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of

the AEP and would increase transparency for Medicare beneficiaries and enrollment counselors on opportunities to change plans. We are committed to exploring updates to the systems and supports designed to aid individuals in making Medicare choices in conjunction with the final rule. Finally, with respect to commenters' concerns about prior authorizations, we note that the April 2023 final rule (88 FR 22206) amended § 422.112(b)(8)(i)(B) to require MA organizations offering coordinated care plans to have prior authorization policies that provide for a minimum 90-day transition period for any ongoing course(s) of treatment for new enrollees even if the course of treatment was for a service that commenced with an out-of-network provider. While this does not fully guarantee coverage of services authorized through prior authorization by another plan, it does provide some protection against repetitive prior authorization processes as a result of a change to a new MA (or MA–PD) plan.

Comment: Several commenters recommended CMS consider exceptions or modifications to the SEP proposals to allow enrollment into additional MA–PDs outside of the AEP or MA–OEP. A few commenters noted dually eligible individuals should be able to choose between any MA plan during a Medicaid MCO open enrollment period, when a Medicare enrollee is newly eligible for Medicaid, and in States that do not have any Medicaid managed care or carve dually eligible individuals out of Medicaid managed care. Some commenters suggested maintaining the quarterly dual/LIS SEP in States that do not have D–SNPs or integrated D–SNPs so that individuals can enroll in other types of MA–PDs and have continued access to supplemental benefits and coordination of care and services. A commenter suggested keeping the quarterly SEP but allowing two changes during the quarter of Medicaid renewal to allow dually eligible individuals an additional opportunity to algin their Medicare and Medicaid coverage. A commenter suggested allowing dually eligible individuals to elect any MA–PD plan that is offered by an integrated delivery system or maintains a provider network in which the majority of physicians do not accept, or serve very few, Traditional Medicare enrollees. A commenter also requested that CMS consider applying the SEP changes on a State-by-State basis to take into account unique situations for States where enrollees would be adversely limited in choice and access.

Response: We appreciate commenters' suggestions to modify the SEP proposals. While we acknowledge that States may have their own enrollment policies and election periods, we believe the benefits of the SEP proposals, including the opportunity to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care, outweigh the potential drawbacks. Further, dually eligible individuals would still have the ability to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits. For example, dually eligible individuals that have a change in their Medicaid status—including newly gaining Medicaid eligibility—continue to have access to an SEP at § 423.38(c)(9).

We recognize dually eligible individuals will not be able to use the integrated care SEP in States that currently do not have Medicaid managed care plans, carve dually eligible individuals out of Medicaid managed care, or do not have integrated D–SNPs (that is, do not have Medicaid MCOs that are affiliated with D–SNPs or opportunities for aligned enrollment). Allowing exceptions to the proposed SEPs for certain plans or on a State-by-State basis would increase complexity for dually eligible individuals and enrollment counselors in understanding eligibility for the SEP and pose challenges for CMS to monitor usage.

Comment: Some commenters recommended that CMS monitor and publicly report SEP utilization. A commenter recommended that CMS create a transparent, accessible central data source on SEP usage and availability that would be available to SHIPs, State ombudsman programs, and State Medicaid agencies to support administration and oversight of SEP usage by MA plans. The commenter opined that making such data available would improve transparency for parties that support Medicare beneficiaries and dually eligible individuals to understand their Medicare enrollment options and increase visibility into potentially aggressive or misleading marketing behaviors, including targeting by D–SNP look-alikes. A commenter urged CMS to monitor SEP utilization patterns to ensure that plans are not dissuading individuals from staying enrolled and that there are no other issues that may be causing an individual to switch plans or leave MA. Another commenter encouraged CMS to collect monthly SEP utilization data and publicly report it at least annually. A commenter advised CMS to closely monitor for unintended effects on D–SNP enrollees who make multiple plan switches within a year. Citing potential challenges associated with the CMS SEP proposal in States with few or no integrated D–SNPs, a commenter requested that CMS conduct and release an analysis of the proposal's impact on States and individuals on a State-by-State basis.

Response: We thank commenters for their perspectives on this issue. In the proposed rule (88 FR 78569), we discussed concerns with the quarterly dual/LIS SEP creating complexity for SHIP and State ombudsman programs as they do not have access a central data source to determine if someone has already used the quarterly dual/LIS SEP, making it difficult to determine what enrollment options are truly available to dually eligible individuals. Changing the SEP to allow once-per-month usage will reduce complexity for enrollment counselors and individuals. In addition, if both the dual/LIS SEP and integrated care SEP are used in the same month, the application date of whichever SEP was elected last will be the enrollment effectuated the first of the following month.

We are considering making updates to systems and supports, including MPF and HPMS, that help individuals make Medicare choices. One of the considerations is how to show plans available to individuals along with options that align with their Medicaid enrollment.

We will work with States on implementing the policies finalized in this rule and will continue to monitor all aspects and consider future updates as appropriate.

Comment: Many commenters expressed significant concerns about limiting enrollment outside of the AEP to Traditional Medicare and PDPs. A few commenters suggested a revision to the dual/LIS SEP proposal so that dually eligible and LIS eligible individuals who use the SEP to disenroll from an MA–PD and enroll in Traditional Medicare and a PDP would have the ability to return to their former MA–PD within 90 days if they are dissatisfied with their choice.

Response: We appreciate the suggestion to allow individuals to return to their MA–PD plan within 90 days of disenrollment, but we are declining to incorporate it into the final rule. We believe incorporating a change like this could increase complexity for enrollment counselors, plans, and CMS to determine when someone was eligible to go back to their MA–PD plan and cause an increase in churn and disruption with individuals making frequent enrollment changes. However,

individuals may re-enroll where another SEP allows, such as for 5-Star plans. In addition, under current rules, dually eligible individuals can re-enroll into their former MA–PD plan or otherwise make a different plan selection during the AEP, MA–OEP, or where another SEP permits.

We acknowledge that the SEP changes will limit enrollment opportunities in MA–PDs and non-integrated D–SNPs during certain times of the year. We believe the benefits of the SEP proposals will do more to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care.

Comment: A few commenters raised concerns regarding the integrated care SEP and how it would apply in Oregon where some D–SNPs have a unique ownership model with Coordinated Care Organizations (CCO) to provide Medicaid managed care services. The D–SNPs aligned with some CCOs are not considered HIDE SNPs because they are not owned or controlled by the same parent organization as the CCO. The commenters noted many dually eligible individuals would not be able to use the integrated care SEP to enroll in the coordination-only D–SNPs aligned with a CCO. Another commenter suggested allowing dually eligible individuals in Oregon the ability to use the integrated care SEP to enroll in coordination-only D–SNPs that are aligned with a CCO or for CMS to expand the definition of AIP to include coordination-only D–SNPs within a CCO.

Response: We thank the commenters for the additional information and acknowledge that some States have unique Medicaid managed care arrangements. We recognized in the proposed rule (88 FR 78570) there would be some challenges in States with few or no integrated D–SNPs because the lack of FIDE SNPs, HIDE SNPs, and AIPs would limit dually eligible individuals' ability to change their MA–PD plan outside of the AEP, MA–OEP, or as other SEPs permit. We believe the benefits of the SEP proposals nationwide outweigh the potential drawbacks, including that in some States the integrated care SEP we are finalizing at § 423.38(c)(35) may not be fully accessible, in order to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care.

Expanding the definition of HIDE SNP is beyond the scope of this current rulemaking, and we believe that changes of the type recommended by the commenter should be carefully considered and subject to notice and an opportunity for comment by other interested parties, but we will consider the Oregon example for potential future rulemaking.

Comment: Many commenters requested clarification on current SEPs available to dually eligible individuals. Several commenters requested confirmation that the PACE SEP in Part D would still be available for individuals wishing to enroll in or disenroll from a PACE organization. A commenter also noted that PACE participants have been targeted in recent years by some MA–PD plans and D–SNPs encouraging them to disenroll from PACE and requested confirmation the PACE SEP would still be available for beneficiaries to re-enroll in PACE in these situations.

A commenter opposed the SEP changes and requested an exclusion for people who reside in institutions as their needs change frequently, as do the providers who see them. Another commenter suggested keeping the quarterly dual/LIS SEP but allowing individuals to use an SEP if they receive inaccurate information about a plan prior to enrollment or an agent enrolls them without their knowledge. Another commenter requested CMS confirm that D–SNPs with a 5-Star Rating will still be able to enroll individuals using the 5-Star SEP. Finally, a commenter supported the dual/LIS SEP and integrated care SEP and appreciated that CMS noted in the proposal that access to other SEPs will not change.

Response: We appreciate the commenters' request for clarity on the continued availability of current SEPs. We proposed to change the current dual/LIS SEP at § 423.38(c)(4)(i) but otherwise did not propose changes to the existing SEPs specifically mentioned by the commenters and that are available in the Part D program outlined in § 423.38(c). The PACE SEP for Part D enrollees at § 423.38(c)(14) will continue to be available for individuals wishing to enroll in or disenroll from a PACE organization. The institutional SEP at § 423.38(c)(15) will continue to be available when an individual moves into, resides in, or moves out of an institution. The exceptional circumstances SEP at § 423.38(c)(36) will continue to be available when a plan or agent of the plan materially misrepresents information to entice enrollment. The 5-Star SEP at § 423.38(c)(20) will continue to be available for individuals to use once per contract year to enroll in a plan with a Star Rating of 5 Stars. (Corresponding MA SEPs and open enrollment periods for each of these examples are at § 422.62(b)(7), (a)(4), (b)(3)(ii), and (b)(15) respectively.)

We appreciate the commenters' support for the SEP proposals and confirm that our decision to finalize these proposed revisions to the existing dual/LIS SEP and to adopt a new integrated care SEP will not affect the ability of individuals to access other applicable SEPs provided in CMS regulations.

Comment: A commenter questioned whether the proposed dual/LIS SEP changes would limit access for dually eligible and LIS eligible individuals since it would limit enrollment outside of the ICEP or AEP to standalone PDPs. The commenter, citing broader changes to Part D, expressed concern about many plans losing LIS benchmark status in 2025, leaving few PDPs (or only one PDP) per county qualifying as an LIS benchmark plan. The commenter further noted that, if the number of LIS benchmark PDPs is small, our SEP proposals could significantly disrupt enrollee care and lead to negative health consequences for high-need LIS individuals who have limited options among plans that may not cover their prescription drugs or impose new utilization management requirements.

Response: We thank the commenter for their perspective on this issue. While we acknowledge the commenter's concerns, we believe protecting Medicare enrollees from aggressive marketing tactics and reducing complexity for States and enrollment counselors outweigh the potential downsides. Our proposed improvements to the Part D risk adjustment model in the CY 2025 Advance Notice [221] would improve payment accuracy for Part D plans, including those that disproportionately serve enrollees with LIS, and we believe this will help foster a competitive market of PDPs. We will continue to monitor the availability of LIS benchmark PDPs over time. Further, dually eligible individuals would still be able to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits.

Comment: A few commenters raised concerns about the impact of the SEPs on access to providers and services. Other commenters noted that many dually eligible individuals need to change plans due to a change or loss in provider participation during the year or due to a change in need for a service

[221] Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

that not all plans may cover and would use the quarterly dual/LIS SEP to make midyear changes in enrollment. They further stated that in some service areas there may be a limited number of certain types of providers, resulting in in long waiting lists for individuals; as such, the proposed dual/LIS SEP would limit the ability to change plans outside of the AEP and could result in a lack of access to adequate care.

Response: We acknowledge the commenters' concerns and agree that continuity of care and mitigating disruption associated with plan changes is important for dually eligible individuals. However, we are not persuaded that the SEP proposals themselves increase the risk for service or provider disruptions compared to what is currently in place.

Comment: Some commenters responded to our solicitation in the proposed rule for comments on whether to use our flexibilities at section 1851(f)(4) of the Act (as cross-referenced at section 1860D–1(b)(1)(B)(iv) of the Act) and at § 423.40(c) to establish a Medicare enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP at § 423.38(c)(4). A few commenters supported the SEP changes but encouraged CMS not to make further adjustments to enrollment effective dates. One commenter acknowledged the real confusion misaligned enrollment dates present but believed the obstacles do not outweigh the benefits of current policy. The commenter believed that harm from misaligned enrollment dates today is mitigated by the fact that most individuals make their enrollment choices prior to the Medicaid cut-off dates, and suggested CMS work with States, SHIPs, D–SNPs, agents and brokers, and State enrollment vendors (including enrollment brokers that meet the requirements at section 1903(b)(4) of the Act and § 438.810) to clearly convey effective enrollment dates. Another commenter supported changes to the enrollment effective dates, noting it would more effectively support exclusively aligned enrollment. The commenter asked if States may direct specifics of enrollment date alignment via SMAC contracts. Another commenter recommended aligning enrollment dates between Medicare and Medicaid when feasible, while another commenter noted it may be additionally burdensome for States to align Medicaid enrollment effective dates with Medicare under a monthly SEP. Another commenter noted that misaligned enrollment effective dates between Medicare and Medicaid cause delays for enrollees in accessing LTSS but acknowledged that aligning start dates would be difficult to achieve. The commenter suggested CMS work with States, enrollment brokers, and plans to clearly convey effective enrollment dates so States can make Medicaid cut-off dates closer to Medicare enrollment effective dates.

Response: We thank the commenters for their thoughts on the option to use our statutory authority at section 1851(f)(4) of the Act (as cross-referenced at section 1860D–1(b)(1)(B)(iv) of the Act) to establish a different enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35). Upon further consideration, we have decided that, as of now, we will not establish a Medicare enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP at § 423.38(c)(4). We will continue to work with States, D–SNPs, SHIPs, and other parties to strengthen communication to dually eligible individuals with respect to enrollment start dates of Medicare and Medicaid plans. Further, we note that such enrollment flexibilities may not be specified through the SMAC, as Federal regulation supersedes State flexibility in the SMAC, and as no such flexibility is adopted through Federal regulation, the option to change or delay Part D enrollment effective dates is not available to States through the SMAC.

Comment: One commenter noted the potential for increased complaints—including marketing misrepresentation complaints—in the HPMS Complaint Tracking Module (CTM) under the SEP proposals. The commenter noted it is possible dually eligible individuals will disenroll from an MA–PD plan, change their minds after enrolling in the new Part D plan before the next available open enrollment period, and subsequently open a CTM with their current integrated D–SNP in order to receive an SEP to disenroll (enrollees who open a marketing misrepresentation CTM against a plan may receive an SEP to disenroll if they received misleading or incorrect information leading them to enroll in a new plan). The commenter contends this creates a loophole to our SEP policy such that dually eligible enrollees can elect a non-integrated plan outside the AEP and, therefore, the commenter requests that CMS update the CTM to ensure only valid complaints result in a marketing misrepresentation SEP.

Response: We thank the commenter for raising the potential increases to CTMs. We appreciate the concern this commenter raises, and we will monitor whether the proposed SEPs lead to increased complaints to D–SNPs in the CTM to determine whether we need to make further adjustments to the CTM in response. However, we do not agree that marketing misrepresentation CTMs—a narrow but important protection for enrollees who receive misleading or incorrect information causing them to make an enrollment change—create a loophole to our SEP proposals sufficiently large enough to undermine their intent. Indeed, the vast majority of MA and Part D enrollees do not qualify for the dual/LIS SEP. Therefore, if marketing misrepresentation CTMs are as manipulable as the commenter suggests, we likely would be experiencing such manipulation on a widespread basis currently among non-dually eligible individuals. However, we do not believe this to be the current reality.

Comment: Many commenters offered support for the D–SNP enrollment limitation proposals at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii). Commenters appreciated CMS's efforts to align enrollment between integrated D–SNPs and Medicaid MCOs, and to limit the number of D–SNP offerings per service area where a D–SNP, its parent organization, or a related MA organization under the same parent organization offers a Medicaid MCO. Commenters noted that integrated models that operate with exclusively aligned enrollment are better equipped to ensure true integration for full-benefit dually eligible individuals. Some of these commenters also appreciated the phased approached offered in the proposed rule. Additional commenters noted that the proposal to limit the number of D–SNPs offered by a parent organization would simplify plan options, reduce confusion for individuals, make it easier for States to track enrollment, and perform oversight and quality improvement with their plans. Commenters noted a reduction in D–SNPs would also reduce harmful marketing practices. Other commenters expressed appreciation for the proposed requirement that parent organizations only offer one D–SNP in a service area where the parent organization also offers a Medicaid MCO, as it would simplify options counseling to individuals, improve provider billing, and reduce barriers to Medicaid covered services like LTSS, dental, and transportation.

Response: We thank the commenters for the support. We similarly believe our proposals would increase the percentage of D–SNP enrollees who are in aligned

arrangements, reduce the number of D–SNP options overall and mitigate choice overload, remove some incentives for agents and brokers to target dually eligible individuals, simplify provider billing and lower the risk of inappropriate billing, and promote integrated care and the benefits it affords, like improved care coordination, integrated materials, and unified appeals and grievance processes.

Comment: Numerous commenters supported the proposal at § 422.514(h)(1)(i) intended to reduce choice overload and create more clear and meaningful plan options for dually eligible individuals. One commenter noted this policy would simplify plan options, reduce confusion for individuals, and make it easier for States to track enrollment, coordinate care, and perform quality improvement with their plans. Another commenter noted the removal of duplicative plans from the market would increase the likelihood that an individual will select a D–SNP. Another commenter felt that multiple plans operated by the same company is not only confusing for individuals dually eligible for Medicare and Medicaid, but also are very difficult for care coordinators assisting those individuals. Another commenter supported the limitation and noted that while this would limit dually eligible individuals' choice of plans, individuals currently struggle with the number of choices and often lack the resources to discern amongst numerous coverage options. They further stated that limiting the number of plans with meaningful differences would incentivize companies to build up their D–SNPs' networks and benefits and make it easier for individuals to make an enrollment choice.

Response: We thank the commenters for their support. We agree that the proposals would simplify D–SNP options, reduce confusion among dually eligible individuals and the options counselors that support them, and generally make plan choices more meaningful for dually eligible individuals, their families, advocates, and enrollment counselors. We similarly agree that a reduction in the overall number of D–SNP options will incentivize MA sponsors to invest in their integrated D–SNPs across markets.

Comment: Numerous commenters opposed the enrollment limitation proposals. Several of these commenters acknowledged or agreed with CMS's efforts to facilitate better alignment of enrollment between Medicare and Medicaid and simplify Medicare options for dually eligible individuals but had concerns with the details of the proposals. Many commenters were concerned about the potential of the proposal to limit the number of D–SNPs offered by the same parent organization in a given service area to negatively impact individual choice. A commenter expressed particular concern regarding the effects of this policy in States that have D–SNPs and Medicaid managed care, but no current requirements for EAE. The commenter believed that, unless CMS's intent is that all MA organizations must offer an affiliated Medicaid MCO and move to EAE, narrowing choices would adversely limit dually eligible individuals' choices, and by 2030 would limit the number of supplemental benefits offered by D–SNPs. Another commenter asked that CMS assess impact on SMACs and whether D–SNP relationships are positively or negatively impacted. Finally, another commenter noted that plans offer multiple PBPs to allow them to tailor benefits for a particular population, and the proposal would remove a plan's ability to do so.

Response: We thank the commenters for their perspective. We acknowledge that the enrollment limitations—both as proposed and as finalized at § 422.514(h) in this rule—may reduce the number of available D–SNP options for dually eligible individuals. As noted in the proposed rule (88 FR 78575), this is by design and a way to address the choice overload faced by dually eligible individuals, their families, and enrollment counselors. We clarify that these policies only apply to an MA organization where it, its parent organization (as defined in § 422.2), or any entity that shares a parent organization with an MA organization also contract with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service area (that is, in a service area that overlaps in full or in part with the service area of the MA organization's D–SNP(s)). In applying the enrollment limitations in § 422.514(h), we will follow corporate ownership to the highest level, rather than looking only to the immediate owner of an MA organization or other, related entity, consistent with the definition of parent organization as meaning the entity that is not a subsidiary of any other legal entity. MA organizations that offer D–SNPs where the MA organization, its parent organization or any entity that shares a parent organization with the MA organization do not offer an MCO are unaffected by the new proposals; such MA organizations may continue to offer coordination-only D–SNPs. Further, even after this final rule takes effect, dually eligible individuals will continue to have more Medicare coverage choices (including Traditional Medicare with a Part D plan, MA–PDs, SNPs, and PACE) relative to their Medicare-only peers.

As noted in the proposed rule (88 FR 78575), we believe the enrollment limitations will have the greatest impact in States that have Medicaid managed care but do not have EAE requirements already, as MA organizations operating D–SNPs in those States will likely choose to consolidate their PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their affiliated Medicaid MCO (that is, the MCO that is offered by the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization) that fully or partially overlaps the D–SNPs service area. We will work closely with States in the event they wish to adjust their State Medicaid agency contracts to require EAE as a result of these policies.

We acknowledge this final rule will limit an MA organization's ability to offer multiple PBPs with tailored benefits, unless one of the exceptions we are finalizing applies. (We discuss the exceptions in detail in response to other public comments later in this section.) We also recognize that plan sponsors offering D–SNPs may also choose to adjust their supplemental benefit offerings as a result of these policies, though we do not believe operating fewer plans to be more administratively burdensome relative to offering many plans. We will monitor the policies' impact to D–SNP supplemental benefits.

Finally, we note we are finalizing § 422.514(h)(1) with a technical modification to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' instead of the more general ''dually eligible individuals'' to match the cross-reference to § 423.772.

Comment: A number of commenters suggested that the enrollment limitations could create barriers for dually eligible individuals in States where they are not required to be in or are explicitly carved out from Medicaid managed care. For example, in New York, only dually eligible individuals with significant long-term care needs are required to enroll in Medicaid managed care, with the majority of dually eligible individuals remaining in Medicaid fee-for-service (FFS). These commenters noted that D–SNPs that also contract with States as Medicaid MCOs can currently enroll individuals

in Medicaid FFS but, under the proposals, those D–SNPs would not be able to enroll these individuals beginning in 2027 and would be required to disenroll them as of 2030. Commenters indicated that these individuals are better served in D–SNPs where they receive coordination of their Medicare and FFS Medicaid benefits. The commenters offered several suggestions for how CMS should address these concerns: (a) limiting the proposal to States that require mandatory enrollment for dually eligible individuals, including those who do not receive long-term care services, (b) implementing a limited exception process for States that would allow MA organizations with an affiliated Medicaid MCO to offer at least one D–SNP PBP that is not exclusively aligned and that can enroll dually eligible individuals who maintain FFS Medicaid coverage and (c) phasing in the proposal over time. Another commenter asked CMS to clarify whether dually eligible individuals in States with voluntary Medicaid managed care would be disenrolled from coordination-only D–SNPs beginning in 2027.

Response: We appreciate the commenters' perspectives but continue to believe that the policy we proposed is appropriate and a practicable means to achieve our goals of furthering integrated coverage for individuals who are dually eligible for Medicare and Medicaid. Applying the D–SNP enrollment limitations to only States that require mandatory enrollment for dually eligible individuals, while not something we explicitly considered in the proposed rule, has some potential drawbacks and we do not think it would further our policy goals as well as proposed § 422.514(h). This alternative would narrow the number of States in which these policies would apply, thus reducing the extent to which we would achieve the benefits described in the proposed rule. It would also raise potential complexity in States where certain subpopulations of dually eligible individuals are mandatorily enrolled, but others are not. Allowing each MA organization with an affiliated Medicaid MCO to offer at least one D–SNP that is not exclusively aligned with its affiliated Medicaid MCO for the purpose of enrolling dually eligible individuals who are enrolled Medicaid FFS would similarly reduce the extent to which we would achieve the benefits described in the proposed rule, create more additional operational complexity for States and CMS to administer and monitor, and would likely be more complicated to explain from a beneficiary communications and messaging perspective compared to the current proposal. Finally, we believe the phase-in outlined in the proposed rule provides ample time for transition; our proposal, which we are finalizing, limits new enrollment to individuals enrolled in both D–SNP and affiliated Medicaid MCO offered under the same parent organization starting in 2027 and then disenrolling those enrollees who do not have aligned enrollment in the D–SNP's affiliated Medicaid MCO in 2030. From the time of issuance of this final rule in 2024, there are two bid cycles and contract years (2025 and 2026) during which D–SNPs with affiliated Medicaid MCOs may prepare for the first phase of enrollment limitations. We decline to incorporate these suggestions in the final rule.

Comment: A commenter stated that the enrollment limitation proposals would seem to have the perverse effect of penalizing MA plans that are aligned with an MCO, while MA plans that are not aligned with an MCO may enroll any dually eligible individual. They further stated that there would be individuals enrolled in Medicaid MCOs that are not eligible for integrated care and requested that CMS clarify the definition of a ''Medicaid contract'' so it refers to only an integrated plan contract since CHIP, TANF, foster care, and other unrelated benefits offered under Medicaid should not be considered contracts for this purpose.

Response: We thank the commenter for their perspective and suggestion. As we described in the proposed rule (88 FR 78575) it may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals were designed to have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new one-time-per month SEP while removing the option to use the dual/LIS SEP to enroll into MA–PDs—including coordination-only D–SNPs. The integrated care SEP would incentivize MA organizations to offer integrated D–SNPs as a means to take advantage of the monthly integrated care SEP that is available to full-benefit dually eligible individuals to facilitate aligned enrollment (that is, for these individuals to enroll only into integrated D–SNPs that are affiliated the Medicaid MCO in which the individual also enrolls).

While the proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) apply (and therefore limit the ability of an MA organization to offer multiple D–SNPs) when an MA organization, its parent organization, or an entity that shares a parent organization also contracts with a State as a Medicaid MCO, the limitation in these regulations applies only when the affiliated Medicaid MCO enrolls dually eligible individuals. Medicaid MCOs that solely enroll other Medicaid populations will not be impacted by this rule. We proposed that dually eligible individuals for purposes of this provision means ''dually eligible individuals as defined in § 423.772,'' but in retrospect realized that we should have used the term ''full-benefit dual eligible individuals'' as defined in § 423.772. Therefore, we have revised § 422.514(h)(1) to clarify that this provision applies only when a Medicaid MCO enrolls full-benefit dual eligible individuals as defined in § 423.772. We have made similar edits to § 422.514(h)(3)(i) and (ii) to specify that we are referring to full-benefit dual eligible individuals as defined in § 423.772. These clarifying edits to the regulatory text have no impact to the enrollment limitations as originally proposed or finalized in this rulemaking at § 422.514(h).

We acknowledge that some Medicaid MCOs may enroll full-benefit dually eligible individuals even when certain Medicaid services, such as long-term supports and services, are carved out. In such scenarios, the rules we are finalizing here will apply, facilitating better access for full-benefit dually eligible individuals to care coordination, unified appeals processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come from aligned enrollment, even if some Medicaid benefits are carved-out. As such, we decline to incorporate these suggestions in the final rule.

Comment: A few commenters expressed concern regarding the impact of our enrollment limitation proposals on partial-benefit dually eligible individuals. They acknowledged that some States permit integrated D–SNPs to enroll both full-benefit and partial-benefit dually eligible individuals; in such cases, our proposal would mean that the full-benefit enrollees are also enrolled in the D–SNP's related

Medicaid MCO while the partial-benefit dually eligible individuals are enrolled only in the D–SNP. These commenters were concerned that partial-benefit dually eligible individuals may experience disruption if they are no longer able to stay in D–SNPs affected by § 422.514(h) after 2030.

Response: We thank the commenters for raising this issue and would like to clarify the impact of the new regulations proposed at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and 422.514(h)(2) for partial-benefit dually eligible individuals. We proposed at § 422.514(h)(1)(i) that, beginning in 2027, an MA organization, its parent organization, or any entity sharing a parent organization with the MA organization that also contracts with a State as a Medicaid MCO may only offer one D–SNP for full-benefit dually eligible individuals. Functionally this means that an MA organization can continue to offer one or more D–SNPs for partial-benefit dually eligible individuals when it meets all other applicable requirements (including having a SMAC) even if the MA organization, its parent organization, or another entity (or entities) that share a parent organization with the MA organization offers an affiliated Medicaid MCO in the same service area. While proposed §§ 422.514(h)(1)(ii) and 422.514(h)(2) go on to limit enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in the Medicaid MCO, the MA organization that offers the D–SNP for full-benefit dually eligible individuals is not prohibited by § 422.514(h)(1)(i), (h)(1)(ii), or (h)(2) from offering additional D–SNPs solely for partial-benefit dually eligible individuals. We illustrate the differential impact on D–SNPs serving partial-benefit dually eligible individuals in the hypothetical example provided in Tables HC3 and HC4 in the proposed rule (88 FR 78574) where we noted that MA Organization Gamma could convert HIDE D–SNP Gamma 001 to coordination-only D–SNP Gamma 001 and keep that plan open for partial-benefit dually eligible individuals.

Comment: A few commenters suggested that CMS provide more information on how our proposals would impact States that have Medicaid managed care programs that only cover a subset of Medicaid services, such as long-term services and supports (these are often called partially capitated Medicaid managed care programs). A commenter further expressed concern that the requirement for MA organizations to limit D–SNP enrollment to only those individuals also enrolled in the affiliated Medicaid MCO may adversely impact individuals in specific States, particularly those that also have partially capitated Medicaid programs, such as New York. The commenter recommended that CMS explicitly clarify partially capitated models as another affiliated Medicaid managed care plan option or allow flexibility for State Medicaid agencies to determine Medicaid plan types that should be aligned with D–SNPs. Another commenter requested CMS clarify whether the exception proposed at § 422.514(h)(3)(i) extends to situations in which full-benefit dually eligible individuals are only enrolled in Medicaid managed care plans if they receive LTSS.

Response: We thank the commenters for raising the issue of partially capitated Medicaid managed care programs. As we noted in the proposed rule (88 FR 78574), while the enrollment limitations proposals for non-integrated D–SNPs would apply based on an MA organization having an affiliated Medicaid MCO, we were considering whether they should also apply where an MA organization has other affiliated Medicaid managed care plan options as well, including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). We described how some States use PIHPs or PAHPs to deliver specific categories of Medicaid-covered services, like behavioral health, or a single benefit, such as non-emergency medical transportation, using a single contractor. As we noted in the proposed rule, to the extent the enrollment limitation provisions incentivize an organization to end its Medicaid managed care contracts rather than offer D–SNPs that are subject to the new limitations, that incentive would be stronger for a PIHP or PAHP than an MCO. We continue to believe that applying these proposals to PIHPs and PAHPs could create incentives that are disruptive yet do not significantly further the goals of our proposals. As a result, we do not intend to extend the enrollment limitation policies in § 422.514(h)(1) and (2) beyond Medicaid MCOs or beyond D–SNPs that enroll full-benefit dually eligible individuals. This would mean that an MA organization offering a D–SNP in the same area that it, its parent organization, or an entity (or entities) that share a parent organization with the MA organization contracts with the State only as a PIHP or PAHP would not be subject to the enrollment limitations at §§ 422.503(b)(8), 422.504(a)(20), or 422.514(h). (We direct readers to § 438.4 for definitions of the terms PIHP and PAHP; these types of Medicaid managed care plans cover less comprehensive benefits than Medicaid MCOs.)

We acknowledge, however, that there may be situations where a State Medicaid agency operates multiple Medicaid managed care programs that enroll full-benefit dually eligible individuals. For example, New York currently operates a fully integrated care program using Medicaid MCOs, plus a separate partially capitated program through which the State pays Medicaid capitation to PIHPs to cover long-term services and supports and ancillary benefits but not primary or acute care. If the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization has a Medicaid MCO contract with the State, the provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1)(i) would apply in this example to limit the MA organization's ability to offer D–SNPs in that State to full-benefit dual eligible individuals. However, the exception proposed and finalized at § 422.514(h)(3)(i) would allow the MA organization in this example to offer one D–SNP for full-benefit dually eligible individuals affiliated with the Medicaid MCO and a second D–SNP for full-benefit dually eligible individuals affiliated with the partially capitated PIHP *if* the State requires this arrangement in the SMAC.

Proposed § 422.514(h)(3)(i) established State flexibility to use the SMAC to ''limit enrollment [into D–SNPs] for certain groups'' based on ''age group or other criteria.'' However, upon reviewing comments, we believe the proposed exception at § 422.514(h)(3)(i) was insufficiently clear and warrants clarification for scenarios like those in New York. Therefore we are revising § 422.514(h)(3)(i) to clarify that we will allow an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to *differentiate enrollment* into D–SNPs either (i) by age group or (ii) *to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s).* We believe this revised text better explains our intent for the exception at paragraph (h)(3)(i). As described in the proposed rule (88 FR 78572), this exception allows for States that currently have different integrated D–SNP programs based on age or Medicaid managed program design to continue to operate

these programs and allows States the flexibility to design future integrated D–SNPs with State-specific nuances as to D–SNP eligibility and/or benefit design should the State choose. In the New York context, for example, § 422.514(h)(3)(i) as finalized would give the State the ability to allow an MA organization with which it contracts as both a Medicaid MCO and as a Managed Long Term Care Plan (MLTCP) (the name for NY's PIHP-based program), to operate more than one D–SNP for full-benefit dually eligible individuals in the same service area—one affiliated with the Medicaid MCO and another with the MLTCP—as long as the State specifies this in the SMAC.

Comment: A few commenters expressed concern regarding the potential impact of the enrollment limitation proposals in rural areas. A commenter noted that network adequacy requirements make it challenging for health plans to offer D–SNPs in rural communities. The commenter further stated that Medicaid managed care is not always available in rural areas and was unsure how the proposed rules would impact the coordination-only D–SNPs that may operate there. A commenter also suggested that CMS should do more to ensure that rural communities have improved access to D–SNPs.

Response: We appreciate the perspectives of the commenters and agree that it can be challenging for States and plans to implement managed care in rural communities. Depending on the State, the enrollment limitation proposals may not be applicable or may have a limited impact, particularly in rural areas where both Medicaid and Medicare managed care may be limited. The proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) apply only when an MA organization, its parent organization, or an entity that that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service area. Coordination-only D–SNPs offered by an MA organization that does have an affiliated Medicaid MCO would not be prevented by the rules we are finalizing at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)—in rural communities or other locations—from continuing to operate as they do today.

Other policies designed to improve access to D–SNPs in rural communities are beyond the scope of this current rulemaking, but we will consider exploring opportunities for potential future rulemaking.

Comment: Some commenters expressed concern about the impact of the proposals that limit the number of D–SNPs available in a service area on plan competition and availability. A commenter cautioned CMS against implementing overly burdensome integration requirements that could ultimately lead to fewer plans in a particular service area, reducing competition and innovation. A few commenters questioned whether proposals that limit the number of D–SNPs available in a service area could force high-performing D–SNPs and/or those with expertise in specialized areas such as MLTSS and behavioral health out of State markets. Commenters further noted that there are plans that serve the dually eligible population through D–SNPs that have not historically served the Medicaid managed care population and that most State Medicaid managed care procurements do not evaluate the quality of available D–SNPs in the State, resulting in a situation where 4- or 5-Star plans are prohibited from offering a D–SNP without a Medicaid managed care contract even when those plans have a higher quality rating than D–SNPs or MA plans offered by entities that also offer Medicaid MCOs. The commenter further stated that higher rated D–SNPs typically offer more robust supplemental benefits, including those designed to address health-related social needs. Another commenter similarly suggested that the proposals could result in lower-quality Medicaid plans gaining new D–SNP enrollees. Another commenter suggested that increased market consolidation related to Medicaid procurements could eliminate coordination-only D–SNPs that can serve as pathways to integration for States and offer care coordination for partial-benefit and full-benefit dually eligible individuals who do not meet criteria for enrollment in integrated Medicaid MCOs. A commenter further stated the impact of the proposals would likely vary depending on whether the markets and procurements drive more competition for Medicaid contracts or drive less competition for Medicaid contracts if it becomes easier to be a coordination-only D–SNP in certain markets. They went on to state that larger organizations already offering D–SNPs may have more capacity to respond to a State Medicaid MCO request for proposals (that is, a procurement solicitation) compared to smaller organizations and that States may favor plans with whom they have existing relationships. Another commenter was concerned that the proposals would incentivize States to further limit the number of D–SNPs or other integrated plans with which they contract, either through procurements requiring statewide coverage or other criteria that may make it less possible for smaller and/or local/regional plans to participate, particularly in rural communities. They further state that, in accordance with the July 2021 Executive Order on Promoting Competition in the American Economy (#14036), CMS should evaluate whether these proposals will preserve ''a fair, open and competitive marketplace.''

Response: We appreciate the comments on the potential impact of our proposals on plan competition. We noted in the proposed rule (88 FR 78575) the theoretical possibility that MA organizations that operate both D–SNPs and Medicaid MCOs might elect to participate in fewer competitive Medicaid procurements (or exit Medicaid managed care in ''any willing provider'' States), to be exempted from the proposed restrictions on D–SNP enrollment and on the number of D–SNP offerings permitted in the MA program, which could adversely affect competition and the minimum choice requirements in § 438.52 for Medicaid managed care programs. However, our SEP proposals would have the opposite effect, since only integrated D–SNPs could benefit from the new integrated care SEP, and we believe our proposals, in combination, maintain strong incentives for organizations to compete for Medicaid managed care contracts. Nothing in our proposals or this final rule fundamentally changes the opportunity to compete for State Medicaid managed care contracts or the annual opportunity to apply for an MA contract. While national organizations have certain advantages, our observation has been that many of the organizations that have successfully created fully integrated D–SNPs with EAE—the types of plans relatively advantaged by the policies we are adopting in § 422.514(h) and with the SEPs—are local organizations with community roots. As such, we do not believe this rulemaking will result in excessive consolidation or anticompetitive outcomes. Nonetheless, we will monitor the market over time to ensure it sustains a fair, open and competitive marketplace.

We do not expect our policies, as proposed or as finalized, to drive out high-performing D–SNPs or Medicaid MCOs with specialized experience. While §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii), as finalized in this rule, in combination are intended to result in a reduction in the number of D–SNP options overall, we

are not persuaded that it would necessarily result in loss of high-performing D–SNPs or Medicaid MCOs with specialized experience. MA organizations that have an affiliated MCO and that offer multiple D–SNPs available to full-benefit dually eligible individuals in the same area will have some flexibility in choosing how to consolidate its D–SNPs under this final rule. We believe that this final rule offers significant incentives to ensure high-performing MA and Medicaid managed care plans continue. States that operate specialized Medicaid managed care programs focusing on MLTSS or behavioral health, for example, may be able to utilize the exception at § 422.514(h)(3)(i) to allow more than one D–SNP to be available in the State for full-benefit dually eligible individuals in the same service area by including in the State's SMAC with the MA organization that each D–SNP align enrollment with the eligibility criteria and/or benefit design used in the State's Medicaid managed care program(s). In finalizing our proposal at § 422.514(h) (with modifications discussed throughout this section of the final rule), we are clarifying that the final regulation applies based on an MA organization having an affiliated Medicaid MCO in the same service area; it would not apply to other affiliated Medicaid managed care plan options such as prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) which States use to deliver specific categories of Medicaid-covered services, like behavioral health, or a single benefit, such as non-emergency medical transportation (see further discussion in the proposed rule at 88 FR 78574). As a result, we believe the risk of specialized plans leaving the market is low.

As noted in the proposed rule (88 FR 78751), States have discretion in how they structure their Medicaid managed care programs. This includes whether and how they select Medicaid MCOs to participate in such programs, whether that is through competitive procurements or an ''any willing provider'' approach. As noted in prior response, under our proposals an MA organization, its parent organization or any entity that shares a parent organization with the MA organization that also contracts with a State as a Medicaid MCO could continue to offer one or more D–SNPs for partial-benefit dually eligible individuals.

Overall, we agree with commenters who stated that the impact will vary based on the market. As noted in the proposed rule (88 FR 78575), we believe the impact of these final policies will be concentrated in those States that have Medicaid MCOs but do not have EAE requirements already. We acknowledge that this rulemaking may impact organization decisions about whether and how to participate in certain markets but believe that, on the whole, the policies we are finalizing in this section of the final rule will better serve the dually eligible individuals by furthering opportunities for these individuals to enroll in integrated plans.

Comment: A commenter noted that the enrollment limitation proposals could lead to more D–SNP-only contracts, which may result in lower Star Ratings than other contract structures. The commenter further requested CMS consider the impacts of more D–SNP-only contracts on the Star Ratings program, noting that should D–SNP-only contracts have lower Star Ratings, D–SNPs would have less funds to invest in supplemental benefits that address important health related social needs.

Response: We appreciate the commenter's perspective and agree that the proposals could potentially lead to more States requiring D–SNP-only contracts after 2030, as aligned enrollment and service areas for D–SNPs with affiliated Medicaid MCOs would be Federally required, allowing States to receive the benefits of D–SNP-only contracts. For example, § 422.107(e) provides that States with D–SNP-only MA contracts may have HPMS access for oversight and information sharing, greater transparency on Star Ratings specific to D–SNP enrollees in their State, and increased transparency on health care spending. With regard to concerns that D–SNP-only contracts may result in lower Star Ratings than other MA contracts, we direct the commenter's attention to the April 2023 final rule (87 FR 27765 through 27766) where we addressed similar issues. While we understand the concern that D–SNP-only contracts are rated in comparison to MA contracts that may have few or no dually eligible enrollees, the Star Ratings methodology addresses accuracy of measurement by case-mix adjusting some individual measures in accordance with measure specifications and applying CAI for other measures that are not case-mix adjusted to ensure that factors outside a contract's control are not captured in Star Ratings. In addition, beginning with the 2027 Star Ratings, the HEI reward will be added to incentivize and reward relatively high performance among enrollees with specified SRFs including LIS/DE and disability among contracts, like D–SNP-only contracts, that serve relatively high percentages of these enrollees.

Comment: A commenter requested that CMS assess whether the proposed enrollment limitations for non-integrated D–SNPs could lead to more D–SNP look-alikes as MA organizations try to avoid application of § 422.514(h) and, if so, inquired about the strategies CMS would employ to mitigate such a risk. Another commenter noted that increasing requirements on D–SNPs and States before D–SNP look-alikes are addressed may promote enrollment into less integrated plan options.

Response: We appreciate the commenters' perspectives but do not expect our proposed limitations on enrollment into non-SNP MA plans to increase the number of D–SNP look-alikes. As we stated in the proposed rule (88 FR 78575), under our proposals MA organizations that have multiple D–SNP PBPs available to full-benefit dually eligible individuals and that also have affiliated Medicaid MCOs in the same service area (that is, MCOs offered by the MA organization, its parent organization, or an entity that shares the same parent organization) would likely choose to consolidate their D–SNP PBPs down to a single D–SNP that is aligned with their Medicaid MCO that fully or partially overlaps the D–SNP service area and therefore available to full-benefit dual eligible individuals. Such MA organizations could operate non-AIP coordination-only D–SNPs both for service areas where the MA organization does not have an affiliated Medicaid MCO and for partial-benefit dually eligible individuals. Thus, we expect robust availability of D–SNP options for dually eligible individuals, including partial-benefit dually eligible individuals, to remain and not lead to establishment of additional D–SNP look-alikes. In addition, we proposed (and are finalizing in this rule) a reduction in the threshold for identifying and phasing out D–SNP look-alikes (see section VIII.J). As the final rule is implemented over the transition periods and deadlines specified in § 422.514, we will monitor the D–SNP landscape and enrollment transitions and consider future rulemaking as needed.

Comment: A few commenters urged CMS to monitor the impacts of this rule over time. Several commenters suggested CMS examine the impact of these proposals on individuals and availability of viable plan options over time. A commenter specifically suggested including whether the quality of D–SNPs is impacted positively or negatively by these proposals. Another commenter suggested CMS monitor the

impacts of the changes on the availability of Medicaid managed care plans to better understand if the enrollment limitations encourage, or potentially discourage MA sponsors from applying to offer aligned Medicaid plans, creating an unintended effect on access to or choice among Medicaid managed care plans and by extension, aligned integrated plans. Another commenter asked CMS to monitor trends associated with the SEP proposals to ensure there are no adverse impacts on dually eligible individuals.

Response: We appreciate these comments underscoring the importance of monitoring the impact our rulemaking has on Medicare and Medicaid managed care plans. We agree and will pay close attention to the impact on sponsors as well as States and, most importantly, on dually eligible individuals.

Comment: Several commenters highlighted the potential impact of proposals to limit the number of and align enrollment in D–SNPs in certain service areas on State Medicaid policy. A few commenters expressed concern with what they characterized as the one-size-fits-all and/or top-down approach taken in these proposals and indicated that States need both direction and flexibility to innovate in a way that is appropriate to State-specific landscapes. Another commenter requested CMS consider how these proposals would impact ongoing State efforts to advance integration. Another commenter similarly noted that State autonomy in program design is a cornerstone of the Medicaid program and that aspects of the proposal may not account for the unique structure of certain Medicaid programs, including dually eligible individuals crossing multiple eligibility categories, State choice in benefit inclusion, voluntary vs. mandatory Medicaid managed care, and State procurement timelines. A few commenters acknowledged that States may not be aware of or planning ahead for how current State procurements may impact or be impacted by proposed new requirements for aligned enrollment applicable beginning 2027 and 2030, particularly when Medicaid procurement timelines do not align with MA service area expansion and bid filing timelines. The commenter further expressed concern that the proposed changes could result in unanticipated disruptions where States are making progress toward integration, including those States moving from the Financial Alignment Initiative to D–SNP models.

Response: We appreciate these perspectives. We agree that States have policy interests and goals that shape their unique Medicaid managed care programs; as noted in the proposed rule (88 FR 78571), our intent is to help further support States in their integration efforts while also addressing the significant recent growth in both the number of D–SNPs and the number of dually eligible individuals with misaligned enrollment. We believe the opportunities to reduce choice overload and market complexity where parent organizations offer multiple D–SNP options in the same service area and to provide a truly integrated experience for a greater number of dually eligible individuals by requiring plans to align enrollment outweigh incremental constraints on State flexibility. We also again note the exception to accommodate State policy choices, described in § 422.514(h)(3)(i). We are in close communication with the States planning to transition from the FAI to integrated D–SNPs and will continue to work closely with all States directly and through the Integrated Care Resource Center to provide technical assistance and support for States.

Comment: A number of commenters acknowledged limited capacity and resources at the State level to support integration efforts for dually eligible individuals. Some commenters were concerned that the increasing complexity of Federal regulations, including these proposals, could lead to greater State burden, while others, including MACPAC, recommended CMS offer more technical assistance and educational opportunities to support States, particularly those with limited expertise with Medicare and/or expertise with enrolling dually eligible individuals in managed care. Examples from these commenters included for CMS to work with States to share best practices for building infrastructure needed to facilitate alignment and to facilitate engagement between States, CMS, health plans, and other stakeholders to ensure a seamless transition. Another commenter expressed concern that the proposals combined with limited Medicare expertise among States could dissuade States from pursuing managed LTSS programs as part of the Medicaid programs in the future. Another commenter suggested CMS provide targeted resources to Medicaid agencies that would allow for systems upgrades to implement exclusively aligned enrollment. Another commenter suggested that a portion of the $2 billion CMS estimates in savings from these proposals could be allocated to support States including technical assistance, staffing, and modernization of systems to support integration. A commenter similarly noted that States need investments, both up front and through shared savings models, to invest in staff and systems changes necessary to integrated care.

Response: We appreciate and agree with the comments highlighting the need to support State Medicaid agencies in their efforts to integrate care for dually eligible individuals. We will continue to engage with States to promote integration, including through implementation of this final rule. Our technical assistance vendor, the Integrated Care Resource Center,[222] also provides a range of written and live resources targeted to State Medicaid staff, such as sample contract language for State Medicaid agency contracts with D–SNPs, tip sheets describing exclusively aligned enrollment and other operational processes that support Medicare and Medicaid integration, educational materials and webinars about D–SNPs and highlighting State strategies for integrating Medicare and Medicaid, and one-on-one and small group technical assistance.

Comment: Numerous commenters highlighted the impact of the enrollment limitation proposals on coordination-only D–SNPs. Several commenters noted that the proposals do not impact D–SNPs that do not also, directly or through an affiliated organization, contract with a State as a Medicaid MCO. These commenters expressed concern that this would afford unintegrated D–SNPs more flexibility than integrated D–SNPs, undermining CMS's goal to increase enrollment in integrated D–SNPs and may promote the proliferation of coordination-only D–SNPs. Many of these commenters encouraged CMS to extend the proposal to non-integrated D–SNPs by limiting the number of coordination-only D–SNPs offered by the same parent organization operating in the same service area. A commenter suggested that the enrollment limitation proposals could create churn between unaligned and aligned D–SNPs. Another commenter suggested CMS take steps to reduce the availability of non-integrated D–SNPs, particularly in service areas where integrated D–SNPs are available, by requiring that non-integrated D–SNPs only enroll people who are not enrolled in a Medicaid MCO. Another commenter expressed support for discontinuing coordination-only D–SNPs in 2027. In contrast, another commenter noted the role coordination-only D–SNPs play in providing a starting point for States on which to

[222] *http://www.integratedcareresourcecenter.com.*

build integrated care programs. They further requested CMS require States to support coordination-only D–SNPs as an option for partial-benefit dually eligible individuals as a condition of application of these requirements in order to ensure access for partial-benefit dually eligible individuals and to enable enrollment in coordination-only D–SNPs throughout the transition.

Response: We appreciate the commenters' perspectives. We clarify that we did not propose to eliminate coordination-only D–SNPs in 2027. As we described in the proposed rule (88 FR 78575), it may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals would have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new integrated care SEP. Therefore, we believe our proposals, in combination, would maintain a high level of competition and choice, even while imposing some new constraints. While we thank the commenters for the suggestions on limiting the availability of unintegrated D–SNPs, we believe that they are beyond the scope of this current rulemaking and that such policies should be subject to advance notice and an opportunity to comment by all interested parties before we implement such changes. Finally, as noted in other comment responses, our proposals still would allow for parent organizations with an affiliated Medicaid MCO to continue offering (or newly offer) coordination-only D–SNPs for partial-benefit dually eligible individuals.

Comment: Some commenters expressed support for the exception to the D–SNP enrollment limitation proposed at § 422.514(h)(3)(i). Several of the commenters stated that the proposed exception preserves Medicaid agencies' ability to design D–SNP programs to meet specific populations' needs and requested CMS preserve this administrative flexibility. Another commenter agreed but cautioned this exception should be limited in scope. The commenter also recommend CMS consider adding another exception related to partial-benefit dually eligible enrollees.

Response: We thank the commenters for the support. We believe the exception at § 422.514(h)(3)(i), with the changes discussed in our responses to prior comments in this section, allows for States that currently have multiple integrated D–SNP programs based on age or benefit design in their Medicaid managed care programs to continue to operate these programs and allows States the flexibility to design future population-specific integrated D–SNP programs should they so choose. We agree that the exception should be limited in scope while allowing for this continued State flexibility.

We acknowledge commenters' concerns about the applicability to partial-benefit dually eligible individuals and, as addressed in a previous response, we reiterate that the limitations proposed and finalized at §§ 422.514(h)(1)(ii) and 422.514(h)(2) are specific to enrollment of full-benefit dually eligible individuals and D–SNPs that are open to enrollment by full-benefit dually eligible individuals. An MA organization can continue to offer one or more D–SNPs for partial-benefit dually eligible individuals when it has a SMAC and meets all other applicable requirements even if the MA organization, its parent organization, or another entity (or entities) that share a parent organization with the MA organization offer an affiliated Medicaid MCO in the same service area. Therefore, we do not believe that an additional exception to the enrollment limitations in § 422.514(h)(1) and (2) is necessary to ensure D–SNP enrollment opportunities for partial-benefit dually eligible individuals.

Comment: Several commenters raised questions regarding the timing of the proposals to increase the percentage of dually eligible individuals in aligned plans for Medicare and Medicaid (that is, when the D–SNP limitations will first apply). A few commenters recommended that provisions to limit D–SNP enrollment be implemented before the proposed date of 2027, while several commenters requested that implementation of these provisions, and specifically the proposed SEPs, be delayed. Another commenter indicated that it was unclear when the proposed changes would go into effect.

Response: We thank the commenters for their questions and suggestions regarding the timing of the proposals related to increasing aligned enrollment for dually eligible individuals. As finalized, the SEP policies in §§ 423.34(c)(4)(i) and (c)(35) will be applicable for enrollments that take effect on or after January 1, 2025, while the D–SNP limitation policies will apply as follows:

- The restriction on an MA organization offering more than one D–SNP for full-benefit dual eligible individuals in the same area where the MA organization has an affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2027 under § 422.514(h)(1)(i) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)).
- The limit on new enrollment in a D–SNP offered by an MA organization with an affiliated Medicaid MCO in the same service area to individuals who are enrolled in or in the process of enrolling in the affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2027 under § 422.514(h)(1)(ii) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)). This provision will apply to new enrollments and will not require the D–SNP to disenroll previously enrolled individuals (whether partial-benefit dually eligible individuals or full-benefit dually enrolled individuals) who are not also enrolled in the affiliated MCO.
- The limit on enrollment and continued enrollment or coverage for a D–SNP that is subject to § 422.514(h)(1) to only full-benefit dual eligible individuals who are also enrolled in or in the process of enrolling in the affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2030 under § 422.514(h)(2) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)). This provision will require the D–SNP to disenroll individuals who do not meet the enrollment limitation requirements beginning January 1, 2030.
- The exceptions in § 422.514(h)(3) will apply on the same schedule as the new limitations and restrictions in § 422.514(h)(1) and (2).

We believe these timelines give CMS, States, and MA organizations an appropriate amount of time to make necessary policy and operational updates.

Comment: Many commenters raised operational concerns on, or provided suggestions for, our proposed enrollment limitations. Several commenters requested that CMS confirm the applicability of the proposals to integrated D–SNPs in ''direct capitation arrangements.'' One commenter suggested that in 2027, the alignment proposal would require States to change their processes and would require CMS to create a new process

that links D–SNPs with their affiliated Medicaid MCOs in order to implement the new enrollment limitations. Another commenter raised concerns with respect to State Medicaid auto-assignment processes, stating that dually eligible individuals could find themselves enrolled in a Medicaid plan and a D–SNP from the same organization without making any choice under our proposal. Another commenter expressed concern about the States transitioning the Financial Alignment Initiative (FAI) to D–SNPs in 2026, suggesting those States will be aligning enrollment based on the organization that provides Medicare coverage. The commenter requested that we adjust the timing of the implementation of the proposals to better align with the sunsetting of the FAI demonstrations. Finally, a commenter expressed concerns with the proposed § 422.514(h)(2) based on the commenter's belief that the rule would require certain individuals to be disenrolled both from their D–SNP and Medicaid MCO in 2030 and requested that CMS provide more clarity that D–SNP deeming would occur before a disenrollment.

Response: We thank the commenters for their questions and suggestions. First, we clarify that § 422.514(h), both as originally proposed and as finalized, applies to MA organizations that offer a D–SNP and where the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO and receives capitation payments from the State. This would include what a commenter referred to as ''direct capitation arrangements.''

We also clarify that we did not propose (and are not finalizing) any changes to the process or mechanism for how a dually eligible individual may elect a D–SNP. There is no passive enrollment of individuals into MA plans—including D–SNPs—aside from what is described at § 422.60(g). We did not propose (and are not finalizing) changes to default enrollment provisions or any other passive enrollment provisions for D–SNPs. In addition, we did not propose (and are not finalizing) any changes to the regulation at § 438.54 governing the enrollment process States must use for their Medicaid managed care plans (which may include passive and/or default enrollment procedures).

We clarify that our enrollment limitations at § 422.514(h) apply to D–SNPs regardless of integration status—including HIDE, FIDE, and coordination-only D–SNPs—so long as that D–SNP has an affiliated Medicaid MCO that serves full-benefit dually eligible enrollees in the same service areas as the D–SNP. We acknowledge that the policy will likely mostly apply to D–SNPs with HIDE and FIDE designations, but there are also examples of coordination-only D–SNPs achieving AIP status despite Medicaid benefit carve-outs, as is the case in California. See § 422.561, paragraph (2)(ii).

We understand commenters' concerns with respect to the potential need for States to change operations in reaction to the new D–SNP enrollment restrictions proposal, but we believe the requirements are broad enough that they may accommodate a variety of operational strategies for aligning enrollment between D–SNPs and Medicaid MCOs. For example, we do not believe changes to Medicaid auto-assignment processes will be uniformly required. However, because alignment of new enrollments is not required under § 422.514(h) until 2027 and full alignment is not required until 2030, we believe there is adequate lead time for States and D–SNPs to consider implications of the proposals and adjust operations as needed.

We acknowledge commenters' concerns with respect to the regulation's impact in 2030, when D–SNPs impacted by § 422.514(h) will only be permitted to cover enrollees who are full-benefit dually eligible individuals and enrolled in an affiliated Medicaid MCO. We clarify that there is no requirement that an unaligned enrollee be disenrolled *from a Medicaid MCO* in either 2027 or 2030 as a result of these proposals. The required disenrollment would be *from the D–SNP,* beginning January 1, 2030. In a scenario where a full-benefit dually eligible individual has unaligned enrollment (meaning enrollment in a Medicaid managed care plan other than the Medicaid MCO that is affiliated with the D–SNP), the D–SNP would be required to disenroll the individual, who would remain enrolled in the unaffiliated (unaligned) Medicaid managed care plan, subject to the enrollment rules for the State's Medicaid program. The D–SNP disenrollment must comply with existing rules on disenrollment due to a loss of eligibility. We anticipate D–SNPs will work to align as many enrollees in their affiliated Medicaid MCOs as soon as possible in advance of 2030 but acknowledge that the subsequent disenrollment of unaligned enrollees from the *D–SNP* may be disruptive. We believe the long-term benefits of these provisions—which will increase the number of enrollees in aligned Medicare and Medicaid plans—outweigh the potential disruptions the proposals may cause.

We also note that § 422.514(h) permits D–SNPs to implement periods of deemed continued eligibility to retain enrollees who temporarily lose Medicaid coverage as described in § 422.52(d). These deeming periods are optional unless a State directs a D–SNP to offer a minimum deeming period (which must not exceed 6 months) in the SMAC contract.

We appreciate the comments about States actively working to transition their FAI demonstrations to integrated D–SNPs in 2026. We are working closely with each of these States to keep as many Medicare-Medicaid Plan enrollees as possible connected with integrated care in 2026. Many of these States are currently working on operational processes for exclusively aligned enrollment for their new integrated D–SNP programs, and we do not expect that State operational choices for this program will conflict with any provisions at § 422.514(h). We do not agree that adjustments to the timeline of the D–SNP enrollment restrictions policy are necessary to effectively transition the demonstrations to integrated D–SNPs in 2026.

Comment: Another commenter supported CMS's goal to align D–SNPs with Medicaid MCOs for greater integration but expressed concerns that the rulemaking may negatively affect enrollees if the service areas or provider networks of the Medicare and Medicaid plans are not fully congruent and strongly urged CMS to require full network alignment and transparency before considering a plan to be integrated.

Response: We appreciate the comment. While we agree that completely aligned service areas may provide better transparency to enrollees and options counselors, we clarify that—aside from the service area alignment requirement for FIDE SNP and HIDE SNP designations for 2025 as articulated in the definitions in § 422.2—there is no current requirement nor are we finalizing any requirement that parent organizations offering D–SNPs adjust their service areas to exactly match the service areas of the affiliated Medicaid MCOs. Neither our enrollment limitation proposals nor the enrollment limitation policies we are finalizing have any direct impact on current Medicare or Medicaid network requirements. Nonetheless, we will monitor implementation and assess opportunities to further improve enrollee experiences.

Comment: Numerous commenters raised questions on the operations of

aligning enrollment in Medicare and Medicaid coverage under proposed §§ 422.514(h)(1)(ii) and 422.514(h)(2). A few commenters asked CMS to clarify how these proposals would be implemented in States where exclusively aligned enrollment (EAE) is already in place. In some of these States, dually eligible individuals elect AIP D–SNPs and the State matches the aligned Medicaid plan to the D–SNP; commenters asked CMS to clarify whether that arrangement would remain acceptable under the proposed rule, or if CMS was proposing that the Medicaid MCO be the ''lead'' plan. A few other commenters asked if CMS would use passive enrollment authority to align dually eligible individuals into integrated D–SNPs as a result of this policy. Finally, another commenter requested CMS allow States to implement Medicaid plan enrollment policies, including matching policies, that allow for disenrollment or switching Medicaid plans when a dually eligible individual is electing to enroll in a D–SNP. The commenter also requested that CMS clarify whether D–SNPs could outreach to and encourage unaligned enrollees to enroll in that organization's aligned Medicaid MCO.

Response: We thank the commenters for the questions on the operational impacts of the proposals at §§ 422.514(h)(1)(ii) and 422.514(h)(2). We clarify that we are not requiring that the Medicaid MCO be the ''lead'' plan for the purposes of operationalizing aligned enrollment or EAE, and we believe the requirements as proposed are broad enough that they may accommodate a variety of operational strategies for aligning enrollment between D–SNPs and Medicaid MCOs. Our intent is to strive toward aligned enrollment in D–SNPs—particularly in States that have Medicaid managed care but no EAE requirements—without significantly disrupting current State policies, operations, and program design. This rule does not amend or revise the Medicaid managed care enrollment and disenrollment requirements in §§ 438.54 and 438.56, so the existing flexibilities States have for their Medicaid managed care programs are undisturbed.

With respect to States that have already implemented EAE by ''matching'' Medicaid managed care plan enrollment to an enrollee's D–SNP selection, we confirm that this approach is compatible with the policies proposed and finalized at §§ 422.514(h)(1)(ii) and 422.514(h)(2). For States that have yet to implement EAE but wish to set up systems and operations that would allow their D–SNPs to operate with EAE, we are committed to collaborate on finding feasible operational processes that work best for them, with the aim of being as flexible as possible with the least disruption for dually eligible individuals.

We confirm there is no passive enrollment of individuals into MA plans—including D–SNPs—aside from what is described at § 422.60(g). We did not propose (nor are we finalizing) changes to default enrollment provisions at § 422.66(c) or any other passive provisions in conjunction with our proposals.

Finally, we confirm that no Medicare regulations prohibit D–SNPs from outreach to their current unaligned enrollees. However, there may be additional restrictions to this type of outreach regarding enrollment in a Medicaid managed care plan in State statute, regulations, or SMAC provisions.

Comment: A few commenters raised concerns about the applicability of the enrollment limitations policies on unique Medicaid managed care programs like in Oregon and Puerto Rico. A few commenters raised Oregon's CCOs that consist of a partnership of payers, providers, and community organizations that work at the community level with a community-based governance structure to provide coordinated health care for Oregon Medicaid enrollees. The commenter noted that this model does not currently allow the State to adopt integrated D–SNPs in all circumstances, because in some cases the CCO that holds the Medicaid contract is not under the same parent organization as the D–SNP, which is required for a D–SNP to achieve HIDE or FIDE status. Commenters suggested that CCOs currently provide the level of coordination and integration that CMS is seeking to encourage under this proposed rule and asked CMS to apply the enrollment limitations policy at the CCO level in Oregon. Another commenter questioned whether the proposal that requires an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization to only offer one D–SNP for full-benefit dually eligible individuals in a service area would impact the Medicare Platino program in Puerto Rico. The commenter notes this program has four MA organizations contracted, and these organizations typically offer six D–SNP options each.

Response: We appreciate comments with respect to the applicability of the policy in unique markets like Oregon and Puerto Rico. It is our understanding that most D–SNPs in Oregon already qualify as HIDE SNPs, however we acknowledge there are regulatory barriers for some Oregon D–SNPs to achieve greater integration statuses as defined by CMS and as such cannot be considered affiliated with a Medicaid MCO for the purposes of the proposed requirements at §§ 422.514(h)(1)(ii) and 422.514(h)(2). We will consider future rulemaking to take into account unique organizational structures that may hinder integration efforts as in the case of Oregon.

We understand that Puerto Rico directly contracts with 26 AIP HIDE SNPs, operated by four parent organizations for 2024, with a great deal of service area overlap between these D–SNPs. As is the case in the Platino program, wherever an MA organization that offers a D–SNP, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO for full-benefit dually eligible individuals and receives capitation payments from the State, we consider the D–SNP and Medicaid MCO to be ''affiliated'' under § 422.514(h). MA organizations that offer multiple D–SNPs participating in the Platino program in Puerto Rico will be required to only offer one D–SNP starting in 2027 for full-benefit dually eligible individuals in a service area where the MA organizations, their parent organizations, and entities that share parent organizations with the MA organizations also offer an affiliated Medicaid MCO unless those D–SNPs meet the exception proposed at § 422.514(h)(3)(i). We acknowledge that MA organizations operating in Puerto Rico may choose to consolidate D–SNPs in order to comply with § 422.514(h) and are finalizing the proposed crosswalk exception at § 422.530(c)(4)(iii) to minimize enrollee disruption in connection with such contract consolidations.

Comment: A few commenters raised concerns about the proposed enrollment limitations resulting in negative impacts to the provider community. One commenter urged CMS to explore further how the proposals around integration affect physician and provider communities, specifically providers that serve a significant number of dually eligible individuals. The commenter noted that if there are changes in an individual's enrollment in and alignment with their Medicare and Medicaid benefits, their provider could also change and potentially disrupt continuity of care if that provider does

not have a relationship both with the MCO and the MA plan.

Response: We thank the commenters for their perspectives, but we believe that—because they are designed to increase the percentage of dually eligible enrollees who receive their Medicare and Medicaid benefits through the same organization—the enrollment limitations will ultimately simplify provider billing and lower the risk of inappropriate billing of dually eligible individuals which alleviates provider burden. We will continue to work with health plans, States, and the provider community to ensure providers have timely and accurate eligibility and enrollment information, which we acknowledge is crucial to providing effective and accurate care delivery and coverage for dually eligible individuals.

Comment: A number of commenters expressed support for, or provided questions about, the crosswalk exception proposed at § 422.530(c)(4)(iii) for MA organizations affected by the policies at §§ 422.514(h) and 422.504(a)(20). A few commenters noted the crosswalk exception would help maintain continuity and minimize confusion for enrollees. One commenter requested clarification regarding whether MA organizations can leverage the exception to crosswalk enrollees from a HIDE SNP to a FIDE SNP. The commenter also recommended CMS provide clarifications on the crosswalk methodology and criteria, including if enrollees can only be crosswalked from the affiliated Medicaid plan or if enrollees from another organization's Medicaid plan could also be crosswalked. Another commenter requested clarification regarding whether the crosswalk exception could be used to transition enrollees between D–SNPs that are ''cost-share protected and non-cost share protected.'' This commenter also requested CMS consider expanding the crosswalk flexibility to allow MA organizations to crosswalk enrollees—including full-benefit and partial-benefit dually eligible individuals—across different types of D–SNPs. Another commenter encouraged CMS to ease crosswalk opportunities to better capture the evolving needs of enrollees and State programs. The commenter recommended that CMS allow eligible enrollees from an existing unaligned D–SNP to be crosswalked to another existing unaligned D–SNP of the same plan type offered by the same parent organization but on a different contract to create additional interest from health plans to immediately reduce the volume of plan offerings, eliminating some marketplace confusion as States move along the path to integration.

Response: We appreciate the comments and requests for clarification on the proposed crosswalk exception. We clarify that the crosswalk exception at § 422.530(c)(4)(iii) will allow an MA organization, its parent organization, or an entity that shares a parent organization to crosswalk enrollees from one D–SNP to another across MA contracts, and not just plan benefit packages within a single MA contract, but only when the D–SNPs are being consolidated to a single D–SNP for a service area in order to comply with §§ 422.514(h) and 422.504(a)(20). We emphasize here that this crosswalk exception is about MA enrollment and will not change the Medicaid enrollment of any individual. The new crosswalks may be across contracts (that is, from one contract to another) and across related entities (that is, entities that share a parent organization) but must be of the same plan type; an MA organization may cross enrollees from one D–SNP PPO to another D–SNP PPO but may not crosswalk those enrollees to a D–SNP HMO under new § 422.530(c)(4)(iii). In addition, because this is a new crosswalk exception, the MA organization(s) involved in the crosswalk must request the crosswalk exception from CMS, which will review the request for compliance with the applicable regulation(s). The crosswalk exception is intended to promote continuity for enrollees when an organization consolidates D–SNP offerings in the same service area to comply with §§ 422.514(h) and 422.504(a)(20). If compliance with § 422.514(h) is not the basis for the crosswalk and the MA organization is not consolidating D–SNPs as part of that compliance, it will not be within the scope of new § 422.530(c)(4)(iii). Further the new crosswalk exception is not available until coverage for 2027.

Provided that the preconditions for the crosswalk exception at § 422.530(c)(4)(iii) are met, enrollees may be crosswalked from HIDE SNPs to FIDE SNPs, for example. We would not allow a D–SNP to crosswalk unaligned enrollees, or partial-benefit dually eligible enrollees, into a D–SNP required to operate with EAE, or into a D–SNP subject to the enrollment alignment requirements at § 422.514(h). Additionally, while plan types are taken into account for the purposes of enrollee crosswalks, plan benefit nuances like cost-sharing and supplemental benefits are not considered. Enrollees who are crosswalked into a D–SNP PBP with more cost-sharing responsibilities or different supplemental benefits than their prior D–SNP PBP would be notified of this change through the plan's Annual Notice of Change.

We note that all crosswalk and crosswalk exception requirements in § 422.530 still apply to MA organizations. We believe the new crosswalk exception and current crosswalk requirements offer sufficient flexibility and incentive for D–SNP sponsors to consolidate plan offerings and promote continuity for enrollees in D–SNP types that best meet their needs.

Comment: A few commenters opposed the proposal at § 422.514(h)(3)(ii), which states that an MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may offer (or continue to offer) both an HMO and PPO D–SNP only if they no longer accept new enrollments from full-benefit dually eligible individuals in the same service area as the D–SNP affected by the new proposals at §§ 422.504(a)(20) and 422.514(h). The commenters note that the limitation does not consider product and service area differences that result from having two different D–SNP product types in the same State. Another commenter similarly argued that rural enrollees may need D–SNP PPO access as a result of provider scarcity and suggested that active travelers may value PPO coverage. Finally, another commenter believes that integration, care coordination, and financial alignment can occur even when an MA organization is operating both plan types in a service area, and that the policy unnecessarily limits enrollee plan choice and access to benefits.

Response: We thank the commenters for their perspectives. We recognize MA organizations may choose to adjust service areas as a result of this rulemaking and are not prohibited from providing PPO D–SNPs in more rural areas. As noted in the proposed rule (88 FR 78573), our goals include simplifying the D–SNP market for dually eligible individuals and promoting integrated care through aligned Medicare and Medicaid products. We believe § 422.514(h)(3)(ii), as finalized with clarifications, furthers longer term policy goals while minimizing enrollee disruption in the short term, particularly given that we are not changing the longstanding crosswalk limitations that prohibit enrollee crosswalks between plan types. An MA organization may encourage enrollees in its unaligned D–SNP to join the MA organization's integrated D–SNP and affiliated Medicaid MCO, as allowed in § 422.2264(b)(1) and

consistent with State marketing rules. To improve the clarity of the proposed exception at § 422.514(h)(3)(ii), we are revising the language to specify that if the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the HMO D–SNPs is subject to § 422.514(h)(1), the PPO D–SNP(s) not subject to § 422.514(h)(1) may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to § 422.514(h)(1). Likewise, if the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the PPO D–SNPs is subject to § 422.514(h)(1), the HMO D–SNP(s) not subject to § 422.514(h)(1) may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to § 422.514(h)(1).

Comment: A number of commenters recommended that CMS consider updates to MPF as part of implementing the SEP and enrollment limitation proposals. A few commenters encouraged CMS to develop a strategic communications plan for SEP changes affecting dually eligible individuals. The commenters suggested that CMS work with beneficiary advocates and consider how information is displayed on MPF and relayed through the Medicare call center(s) to make it easy to identify which plans are sufficiently integrated, both in general and for those using this SEP. Since the MA plan selections available during the SEP will differ significantly from open enrollment, other commenters suggested that CMS make updates to MPF that clearly delineate the integrated D–SNPs available based on the enrollee's service area, so they are easily recognizable for dually eligible individuals, caregivers, and SHIPs throughout the year. A commenter urged that CMS do more to convey the value and meaning of integrated D–SNP coverage options to ensure that potential enrollees do not feel they are being punished or limited by the narrower plan choice available when using the SEP but are getting an added benefit—the ability to enroll in a superior plan.

Related to the CMS's proposed enrollment limitations, a commenter noted the need for adding language to MPF explaining why individuals cannot choose a D–SNP listed on MPF, citing Medicare's history of ensuring choice in the Medicare program. Another commenter noted that the enrollment limitation on certain D–SNPs could result in increased confusion among individuals and enrollment counselors. Another commenter emphasized that if CMS adopts the proposal restricting FIDE SNPs to only enroll individuals enrolled in the affiliated Medicaid plan, it is critical for MPF to indicate which benefits are available through the affiliated Medicaid plans.

Response: We welcome the commenters' perspectives on the need for updates to MPF and other means of communication as we implement the SEP and enrollment limitations policies finalized in this rulemaking. As we noted in the proposed rule (88 FR 78574 through 78575), we will consider updates to the systems and supports designed to aid individuals in making Medicare choices. This will include MPF, 1–800–Medicare, HPMS, and other resources to help outline available choices to individuals, SHIP counselors, and others. We recognize such updates will be especially important where dually eligible individuals have choices that vary based on the type of plan and time of year and to clearly show only plans available to individuals along with MA plan options that align their MA coverage with their Medicaid enrollment. We plan to seek input from beneficiary advocates in these endeavors.

As we discuss further in section VIII.G of this final rule on our comment solicitation regarding improvements in MPF, for contract year 2025 we are working to add specific Medicaid-covered benefits to AIPs displayed on MPF.

Comment: A few commenters suggested CMS consider embarking on additional stakeholder engagement work prior to finalizing these proposals. A commenter recommended that CMS convene a diverse set of stakeholders, including consumer advocates and dually eligible individuals, States, and health plans, to minimize potential unintended consequences of the proposals, more robustly consider the unique experiences of Medicaid beneficiaries, and to fully account for the complexities of State Medicaid programs. Another commenter requested that CMS consult further with stakeholders regarding disenrollment processes for integrated plans since States may have different requirements than CMS and with which integrated plans must also align.

Response: We thank the commenters for their suggestion and appreciate the value of robust stakeholder engagement. As noted in the proposed rule (88 FR 78569 through 78571), the SEP and enrollment limitations proposals stemmed from feedback from States, advocacy organizations, health plans, and Medicare options counselors serving dually eligible individuals, among others. The proposals are also in line with previously suggested approaches from MedPAC. We will continue to collect feedback from stakeholders iteratively as we work alongside States and D–SNPs to implement these proposals and may consider future adjustments to the policies if unintended consequences arise.

Comment: Many commenters raised the need to provide technical assistance, funding, and/or sufficient time for training on the proposals to options counselors, SHIPs, and agents and brokers. Another commenter suggested CMS look for ways to enhance Medicare beneficiary education. Finally, a commenter raised the need for CMS to provide better education on the difference in FIDE SNPs and HIDE SNPs and how Medicaid programs cover cost sharing.

Response: We thank the commenters for their suggestions, and we agree it is important that dually eligible individuals understand their enrollment options. Options counselors as well as agents and brokers often play a critical role in assisting this population in making the critical health coverage choices. With respect to the SEP changes and education of SHIP counselors and agents and brokers, we believe that the proposals offer simplified choice options for dually eligible individuals throughout the calendar year, as there will no longer be a need to track quarterly SEP usage. We believe these changes increase transparency and reduce confusion for all parties. We are also considering updates to systems and supports designed to aid individuals in making Medicare choices, including Medicare Plan Finder. Additionally, we often conduct direct beneficiary research to improve our communication approaches with dually eligible individuals and plan to continue to do so in the future to help ensure information available to support individuals' choice of plans is accurate and understandable. We are committed to continuing to develop improved communication strategies and terminology that best resonates with this population as it relates to enrollment options and D–SNP benefits.

Comment: A few commenters stated there is a lack of data that shows integrated plans lead to better results for the populations they serve. A commenter cited a study from the JAMA Health Forum that examined the results

of several years of MA CAHPS surveys. When non-SNP plans were compared to FIDE SNPs, the study found that FIDE SNPs did not perform any better than coordination-only D–SNPs. The commenter also cited an additional study in JAMA Health Forum that compared outcomes between dually eligible enrollees in integrated plans to Traditional Medicare and did not find differences in the reduction of hospitalizations or improvements in care coordination and care management. The commenter indicated, citing these studies, the interconnected proposals would force dually eligible individuals into integrated D–SNPs that could cause harm to enrollees. They additionally cite a study from NORC on behalf of MACPAC where enrollees expressed greater satisfaction with coordination-only D–SNPs compared to those receiving higher levels of integration.

Another commenter acknowledged that the integrated model presents an opportunity for better outcomes and satisfaction but that isn't always the case. They cited MACPAC survey results conducted with enrollees in both integrated and coordination-only D–SNPs and found enrollees in ''highly integrated plans'' rated their plans slightly lower than those in the coordination-only D–SNPs and there were no meaningful differences between the experiences of dually eligible enrollees in plans with higher and lower levels of integration. The commenter added that there is a plethora of data to both support and refute integrated plans leading to better outcomes and without clear data, there can only be assumptions.

Response: We thank the commenters for their thoughts on the issue. While there is limited published research on the benefits of integrated care for dually eligible beneficiaries, we can point to published research from MedPAC, MACPAC, and other research bodies.[223] While some of this research states that evidence for integrated care is currently mixed, we noted in the proposed rule (88 FR 78567), we share MedPAC's belief ''that D–SNPs should have a high level of integration so they have the proper incentives to coordinate care across Medicare and Medicaid'' [224] and MACPAC's ''long-term vision is for all dually eligible beneficiaries to be enrolled in an integrated model.'' [225]

We look forward to more analysis on the experiences of dually eligible individuals and will continue to monitor the growing body of research, as well as continue to carry out our own monitoring, regarding integrated care so that dually eligible individuals have access to seamless, high quality health care.

Comment: A few commenters recommended CMS include an Ombudsman program in the proposal to help navigate the plan landscape for dually eligible individuals. A commenter requested additional flexibility and regulatory changes that would enable Medicaid services to be provided during a D–SNP's period of deemed continued eligibility. Another commenter noted that exclusively aligned enrollment does not address all organizational barriers and silos to system integration and care coordination. The commenter encouraged CMS to consider regulatory action that requires more substantial and meaningful changes to align Medicare and Medicaid to improve outcomes such as one joint health assessment, one personal care plan, one care coordinator, and one interdisciplinary care team across D–SNP and affiliated Medicaid MCO as well as total IT system integration. A commenter highlighted that State Medicaid programs differ, and CMS should establish guardrails and guidance, based on successful initiatives and best practices, to assist States in developing programs going forward. Another commenter was extremely concerned that CMS seems to be prioritizing private MCOs as the primary method of integrating care for dually eligible individuals.

A commenter cited MedPAC's 2013 report that noted I–SNPs perform better than other D–SNPs and other MA Plans on the majority of quality measures and had lower hospital re-admission rates that D–SNPs and C–SNPs. They recommend CMS consider I–SNPs when exploring opportunities for integration with a nursing facility population and provided several factors that could be attributed to I–SNPs achieving better outcomes compared to D–SNPs. Another commenter suggested CMS should enhance awareness of and access to PACE, which offers a truly integrated care option for dually eligible individuals. Another commenter encouraged States use LTSS accreditation programs to meet care coordination requirements for Medicare and Medicaid integration. A commenter recommended CMS implement process and outcome measures for D–SNP enrollee advisory committees (EAC), as increased transparency will help to ensure aspects of proposed regulations such as SSBCI and monthly SEPs have the impact they are intended to have. Another commenter expressed concern that there is a disparity in MA benchmark rates in Puerto Rico, as well as a lack of Medicare Savings Program and LIS benefits for dually eligible individuals in Puerto Rico.

Response: We appreciate the support from commenters who wish to further integrate Medicare and Medicaid benefits via integrated D–SNPs and note that CMS has made progress toward this goal in collaboration with State partners. We received a number of comments not strictly related to the proposals in the proposed rule. We acknowledge and appreciate the suggestions of commenters to include an Ombudsman program in our proposal, make additional regulatory changes around deemed continued eligibility when an individual loses Medicaid, incorporate additional ways to integrate care other than EAE, establish programs based on best practices, and implement process and outcome measures for D–SNP EACs. We also understand that I–SNPs play an important part for individuals receiving care in an institutional setting, the importance of PACE programs for individuals, and the role played by LTSS accreditation programs to meet care coordination requirements for Medicare and Medicaid integration. We recognize that there are lower MA benchmark rates in Puerto Rico and a lack of Medicare Savings Program and LIS benefits for dually eligible individuals. In addition, we acknowledge this final rule focuses largely on improving alignment for dually eligible individuals in Medicare and Medicaid managed care, but we point the commenter to the dual/LIS SEP (88 FR 78569) that allows dually eligible individuals to make a one-time per month election to leave an MA–PD for Traditional Medicare and a PDP. We truly appreciate all of these recommendations; however, these comments are outside the scope of this rulemaking. We will consider exploring opportunities for potential future

[223] See for example: MACPAC. 2020. *Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps. https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf;* Anderson, W.Z. Feng, and S. Long. 2016 *Minnesota Managed Care Longitudinal Data Analysis.* Report to Office of Disability, Aging, and Long-Term Care Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//146501/MNmclda.pdf.*

[224] MedPAC response to Congressional request for information on dual-eligible beneficiaries, page 2, January 13, 2023.

[225] MACPAC response to proposed rule on policy and technical changes to Medicare Advantage and Medicare Part D for contract year 2024 (CMS–4201–P), page 1, February 13, 2023.

rulemaking to address some of these issues.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment at § 423.38(c)(4) on the dual/LIS SEP.

We are finalizing with modifications our proposed amendment at § 423.38(c)(35) to add a new integrated care SEP; based on the comments we received we are narrowing the scope so that the SEP is available only to facilitate aligned enrollment as defined at § 422.2 (this limitation is reflected in a new paragraph at § 423.38(c)(35)(ii)) and clarifying in § 423.38(c)(35)(i) that the SEP is available only for full-benefit dually eligible individuals. Table HC3 summarizes the combined effects of the final SEP proposals.

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Table HF3: Enrollment scenarios under current rules and those finalized in this rulemaking—individual perspective *(Note-table does not include other applicable SEPs)*

Scenarios for dually eligible individuals	Current rules under quarterly dual/LIS SEP	Finalized monthly dual/LIS SEP, integrated care SEP, and enrollment limitations for non-integrated MA-PD plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except full-benefit dually eligible individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable[226]
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter (except the last quarter)	Permitted each month for all LIS eligible individuals and dually eligible individuals
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month for full-benefit dually eligible individuals and available only to facilitate aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	**Current rules**	**As finalized**
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

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We are also finalizing without modification our proposed amendments at §§ 422.503(b)(8), 422.504(a)(20), and 422.530(c)(4)(iii) related to how MA organizations offer and enroll eligible individuals into D–SNPs. We are finalizing § 422.514(h)(1) with a modification to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposed amendment at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization,

[226] During AEP and other available enrollment periods, MA organizations would not be permitted to enroll dually eligible individuals into a D–SNP where such enrollment would not result in aligned enrollment with an affiliated Medicaid MCO offered in the same service area (that is, a Medicaid MCO offered by the MA organization, its parent organization, or another subsidiary of the parent organization).

to offer more than one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with technical modifications our proposed amendment at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accepts new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h).

G. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D–SNPs

Medicare Plan Finder (MPF) is an online searchable tool located on the Medicare.gov website that allows individuals to compare options for enrolling in MA or Part D plans. Medicare beneficiaries can also enroll in a plan using MPF. Each year, we work to improve its functionality by implementing enhancements to MPF. We solicited comment to inform our intent to improve MPF functionality in the future to make it easier for dually eligible MPF users to assess MA plans that cover their full array of Medicare and Medicaid benefits.

In the November 2023 proposed rule, we described at 88 FR 78576 how MPF displays benefits offered by MA and Part D plans, only displaying benefits that are included in the MA plan benefit package (PBP) (that is, Medicare Parts A and B benefits, Part D coverage, approved Medicare supplemental benefits, and Value Based Insurance Design (VBID)/Uniform Flexibility (UF)/ Supplemental Benefits for Chronically Ill (SSBCI)). For most MPF users, this represents the totality of their coverage.

We noted that for applicable integrated plans (AIPs), as defined at § 422.561, D–SNP enrollment is limited to those individuals who also receive Medicaid benefits through the D–SNP or an affiliated Medicaid managed care organization (MCO) under the same parent organization. For these D–SNPs, the benefits listed in MPF accurately reflect those covered by Medicare but do not reflect all the benefits available to all enrollees in the D–SNP.

We provided an example that in most States, all dually eligible individuals who qualify to enroll in an AIP would have access to Medicaid-covered non-emergency medical transportation (NEMT). However, MPF currently only displays NEMT as a covered benefit for any MA plan if it is also covered as an MA supplemental benefit. As such, all other things equal, an MA plan that offers NEMT as an MA supplemental benefit appears in MPF to have more generous coverage than an AIP that does not cover NEMT as an MA supplemental benefit but does cover it under the affiliated Medicaid MCO contract.

We noted in the proposed rule that information about only Medicare benefits covered by MA plans available to the individual, although accurate, may not provide as much information to dually eligible MPF users as would be beneficial, since the combination of available Medicare and Medicaid benefits available through some integrated D–SNPs may be greater than the Medicare benefits reflected in MPF. It may also create a perverse incentive for D–SNPs to offer certain types of supplemental benefits for Medicare marketing purposes even when the same services are already available to all enrollees in the plan through Medicaid.

We described our belief that there is an opportunity to better inform dually eligible MPF users. For AIPs, we noted that we were considering adding a limited number of specific Medicaid-covered benefits (for example, dental, NEMT, certain types of home and community-based services, or others) to MPF when those services are available to enrollees through the D–SNP or the affiliated Medicaid MCO. We indicated that we would limit this functionality to AIPs, because in such plans all enrollees—by definition—receive Medicaid benefits through the AIP.

We noted that we would not include in the MPF display any Medicaid benefits that are available but only through a separate carve-out. Consider, for example, a State in which NEMT is available to dually eligible individuals but through a Statewide vendor separate from the AIP. In this instance, displaying NEMT in MPF would accurately represent that all D–SNP enrollees have coverage for NEMT in Medicaid, but it would not accurately characterize the D–SNP's role (or the role of the affiliated Medicaid MCO offered by D–SNP parent organization) in delivering the service.

We continue to consider whether to indicate which services are Medicare supplemental benefits and which are Medicaid, weighing whether the additional information would be worth the added complexity.

We noted at 88 FR 78576 that displaying Medicaid benefits in MPF, even with the limitations described above, would present new operational challenges for CMS. We have not historically captured the necessary information for AIPs or other D–SNPs in a systematic manner to populate MPF with information about Medicaid benefits covered by D–SNPs, although we could potentially capture the necessary information by providing a mechanism for States or D–SNPs to report it to us annually using HPMS. We solicited comment on the practicality and means for accomplishing this. We also expressed interest in stakeholders submitting comments about any features from the My Care My Choice website at *https://mycaremychoice.org/en* that are particularly helpful for individuals in understanding and making plan choices.

Such enhancements to MPF would not require rulemaking. We solicited comments on the concepts described above to inform our decision about whether and how to implement changes to MPF along these lines.

We are not responding to each specific comment submitted on this comment solicitation, but we appreciate all the comments and interest on this topic. We will continue to take all concerns, comments, and suggestions into account as we work to address and develop policies on these topics and may reach out to commenters for further discussion. We provide a high-level summary of comments submitted regarding key topics raised by commenters.

Comment: Numerous commenters expressed support for improving MPF functionality for dually eligible MPF users, specifically by displaying Medicaid benefits on MPF. A few commenters recommended that CMS not exclude in the MPF display any Medicaid benefits that are available but only through a separate carve-out. A commenter requested that information added to the MPF for AIPs also include benefits available through Medicaid fee-for-service, such as dental. Another commenter agreed with CMS excluding carved-out Medicaid benefits from MPF.

Response: We appreciate the widespread support we received from commenters related to the concept of adding specific Medicaid-covered benefits to integrated D–SNPs displayed on MPF when those services are available to enrollees through the D–SNP or an affiliated Medicaid MCO. We are working on this for contract year

2025 and intend to include a limited number of specific Medicaid covered benefits on MPF when those services are available to enrollees through the D–SNP or the affiliated Medicaid MCO. We continue to improve functionality in MPF for dually eligible individuals, appreciate all the commenters' perspectives on improving their experience, and will consider them as we discuss future updates.

We also appreciate the commenters sharing their concerns about not displaying on MPF any carved out Medicaid benefits and including Medicaid FFS benefits. We will consider these suggestions as we discuss future updates to further enhance MPF functionality.

Comment: Several commenters expressed concern about the accuracy of the Medicaid benefit data and the ability to update it off-cycle. Some commenters also provided suggestions on the process for collecting the Medicaid benefits data. A commenter suggested that CMS consider developing, maintaining, and updating a list of Medicaid benefits covered by Medicaid MCOs in each State from State Medicaid agencies.

Response: We appreciate the commenters for sharing their concerns. Starting for contract year 2025, we plan to collect the Medicaid benefit data from the States using HPMS and will work with the States to verify its accuracy. In late summer each year, we provide two opportunities for MA plans to preview their upcoming contract year drug pricing and plan benefits prior to the data going live on MPF in October. We expect these to be opportunities to ensure accuracy of the Medicaid benefit data. We agree with the need to ensure the Medicaid benefit information is accurate and will consider the commenters concerns when implementing this process.

Comment: Several commenters believed that it was necessary to distinguish between Medicare supplemental and Medicaid benefits while a few did not. A commenter believed that dually eligible beneficiaries probably do not distinguish between the benefits they receive under Medicare and Medicaid.

Response: We appreciate the commenters sharing their perspectives. We will take the comments into consideration when weighing whether this additional information to distinguish whether benefits are covered under Medicare versus Medicaid is worth the added complexity.

Comment: Several commenters provided positive feedback on the My Care My Choice website saying that it was user-friendly and clearly conveyed complex information. A commenter did provide feedback from a study their organization conducted that indicated the tool was not being heavily used in the three focus group States and that the information it contained could be obtained through other resources.

Response: We appreciate commenters taking the time to provide feedback on their experiences with the My Care My Choice website and will consider the feedback as we discuss future updates to further enhance MPF's functionality.

Comment: Commenters also recommended:

- Updating the search and filtering options/functionality in MPF to prioritize D–SNPs over non-D–SNP MA plans when displayed on MPF.
- That the level of integration for D–SNPs be designated, defined, and/or prioritized for dually eligible users when using MPF to search for plans.
- Adding the ability for users to select more than one option on the ''Help with your costs'' MPF web page and concern that the results page still displayed Part B premiums for which dually eligible users may not be responsible.
- Providing definitions or explanations of terms and/or using more simplified language in general on MPF and specifically when describing D–SNPs and integrated plans.
- That MPF include functionality for more information about cost sharing and protections for dually eligible beneficiaries, for example by including the State Pharmaceutical Assistance Program in MPF.
- Including information about provider networks, Medicaid eligibility for D–SNPs, home and community-based alternatives like PACE.
- Displaying SHIP and/or state Medicaid agency contact information.

Response: We appreciate the commenters for sharing their perspectives. We will consider them as we discuss future updates to further enhance MPF's functionality.

H. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D–SNPs

We, along with our State partners, have worked to create integrated care options for dually eligible individuals. When individuals choose to enroll, we want the enrollment process to be easy to navigate. Unfortunately, there remain technical challenges that can impede the ease of enrollment in integrated D–SNPs, including misalignment of Medicare and Medicaid enrollment processes, start dates, and related operational challenges for States and plans, as well as potentially confusing non-integrated enrollee communication materials.

In the November 2023 proposed rule, we described at 88 FR 78576 how, in the FAI, CMS delegated eligibility and enrollment functions for Medicare-Medicaid Plans (MMPs) to States by waiving regulations at 42 CFR 422, Subpart B, and how many States have leveraged their State Medicaid enrollment vendors (including enrollment brokers subject to the limitations in section 1903(b)(4) of the Act) to operationalize enrollment, eligibility, or both. The proposed rule outlined the multiple purposes State enrollment vendors serve within the FAI, including effectuating Medicare and Medicaid enrollment simultaneously, serving as an unbiased source of information, and reducing the risk of real or perceived conflicts of interest when plans initiate enrollment directly.

We also described how, outside of the FAI, dually eligible individuals elect MA plans, including D–SNPs, by enrolling directly with the plan, or through agents or brokers, or via 1–800-Medicare and the Medicare Online Enrollment Center. We noted how this creates special challenges for D–SNPs that have exclusively aligned enrollment (EAE) with affiliated Medicaid MCOs because these D–SNPs then need to separately coordinate enrollment of the dually eligible individual into the D–SNP's affiliated Medicaid MCO. We described how some States have expressed interest in leveraging State enrollment vendors, including enrollment brokers as described in section 1903(b)(4) of the Act, to effectuate EAE for integrated D–SNPs and their affiliated Medicaid MCOs.

We noted that we are assessing ways to promote enrollment in integrated D–SNPs, work toward an integrated D–SNP enrollment process that is operationally practical for CMS and States, create alignment—to the extent feasible—between Medicare and Medicaid managed care enrollment start and end dates, protect beneficiaries from abusive enrollment practices, and streamline beneficiary messaging and communication related to enrollment.

1. Current Opportunity for Use of State Enrollment Vendors for Enrollment in Integrated D–SNPs

In the proposed rule, we described at 88 FR 78577 how States can utilize Medicaid enrollment vendors for enrollment in integrated D–SNPs through requirements in the SMAC required by § 422.107. We use the term ''enrollment vendor'' as meaning

enrollment brokers that meet the requirements at section 1903(b)(4) of the Act and § 438.810. We noted that States may thus require D–SNPs to contract directly with the State's enrollment vendor to verify D–SNP eligibility and effectuate D–SNP enrollment transactions. We noted that while these contracts could govern the respective obligations of the broker and the D–SNP, they would have to be uniform for all D–SNPs in the State, and noted that in order to avoid a violation of section 1903(b)(4) of the Act and §§ 438.71(c)(2) and 438.810 regarding a broker having a financial interest in a provider or managed care plan in the State, the State (instead of the plan) would have to compensate its enrollment broker for performing these functions. We also noted how D–SNPs would still be subject to existing regulations at § 422.504(i), maintaining ultimate responsibility for adhering to and complying with all terms and conditions of their contract with CMS.

We described how States can implement, and require of D–SNPs, specific messaging directing dually eligible individuals to take enrollment actions via the State's enrollment vendor only, and how States could choose which functions to direct the D–SNPs to contract with the enrollment vendor for via the SMAC. We also described the process States could require of D–SNPs to verify eligibility and effectuate enrollment. We noted how requiring D–SNPs to contract with a State's enrollment vendor for enrollment and eligibility functions could create a simpler, streamlined enrollment experience for dually eligible individuals and may reduce the risk of misaligned Medicare and Medicaid enrollment. We described how, as in the FAI demonstrations, the State's enrollment vendor would need to implement Medicare managed care eligibility and enrollment policies. We also noted how, like the FAI demonstrations, States can prohibit D–SNPs, via SMACs, from using agents and brokers to perform the activities described in §§ 422.2274 and 423.2274.

We solicited comment on the feasibility of requiring integrated D–SNPs to contract with State enrollment brokers, as well as any specific concerns about States implementing it. We also solicited feedback on any concerns we should consider with States requiring (using the SMAC) D–SNPs to route enrollment through the State enrollment vendor, as well as whether there are any Federal regulations, other than or in addition to the limitations on enrollment brokers under section 1903(b)(4) and §§ 438.71(c) and 438.810, that interested parties view as an impediment to this option.

We are not responding to each specific comment submitted on this comment solicitation, but we appreciate all the comments and interest on this topic. We will continue to take all concerns, comments, and suggestions into account as we work to address and develop policies on these topics and may reach out to commenters for further discussion. We provide a high-level summary of comments submitted on a few key topics, including those we believe require clarification.

Comment: Several commenters expressed concern with requiring integrated D–SNPs to contract with State enrollment vendors and believed that CMS was proposing a Federal requirement to do so. A commenter stated that requiring D–SNPs to contract directly with State enrollment vendors would add administrative burden for plans, vendors, and enrollees and recommended that CMS not pursue this requirement. Another commenter expressed a belief that this proposal would restrict independent brokers from enrolling beneficiaries in D–SNPs. Another commenter encouraged caution and robust oversight if CMS decides to permit States to use enrollment vendors to enroll individuals dually eligible into D–SNPs.

Response: We clarify that we did not propose any new policy to impose a Federal requirement for D–SNPs to contract directly with State enrollment vendors. Rather, in the November 2023 proposed rule, we sought input on the feasibility of existing opportunities for States to require, through their SMACs, that D–SNPs contract with the State's enrollment vendors.

Comment: A number of commenters expressed support for the idea of States requiring D–SNPs to contract with State enrollment vendors for enrollment in integrated D–SNPs. Several commenters believed this approach could better align enrollment between a D–SNP and an affiliated Medicaid managed care plan and reduce the potential for misalignment. Some commenters emphasized that such an approach would require robust oversight, monitoring, and training for State enrollment vendors. A commenter recommended that CMS provide technical assistance to States to ensure vendors receive education on working with dually eligible individuals. Other commenters suggested that additional resources be invested in State Health Insurance Assistance Programs (SHIPs) as an alternative to requiring D–SNPs to contract with State enrollment vendors. A commenter noted that SHIPs are uniquely positioned to help dually eligible individuals understand their enrollment choices, and recommended CMS require SHIP contact information be included on all plan outreach to beneficiaries. Another commenter suggested that CMS work with States to create State-specific Medicare information.

Response: We thank the commenters for their support and feedback on this approach. These comments will help inform our work with State partners to promote enrollment in integrated care.

2. Medicaid Managed Care Enrollment Cut-Off Dates

The proposed rule described a challenge of applying FAI enrollment processes outside the demonstration context: alignment of Medicaid and Medicare managed care enrollment start and end dates. Sections 1851(f)(2) and 1860D–1(b)(1)(B)(iv) of the Social Security Act, and regulations codified at §§ 422.68 and 423.40(c) respectively, generally require that Medicare enrollments become effective on the first day of the first calendar month following the date on which the election or change is made, although section 1851(f)(4) of the Act and §§ 422.68(d) and 423.40(c) allow CMS flexibility to determine the effective dates for enrollments that occur in the context of special enrollment periods. Medicaid managed care regulations at § 438.54 do not specify the timelines or deadlines by which any enrollment must be effective.

We described how some States have cut-off dates after which enrollment in a Medicaid managed care plan is not effectuated until the first calendar day of the next month after the following month. If a dually eligible individual is trying to enroll in an integrated D–SNP at the end of a month in a State with a Medicaid managed care enrollment cut-off date, there could be a monthlong lag between their Medicare managed care effective date and Medicaid managed care effective date. We noted how the lag in start dates between Medicare and Medicaid services for an integrated D–SNP can be confusing to enrollees, operationally challenging for integrated plans, and difficult to describe in plan materials.

We noted our interest in learning more about reasons for implementing Medicaid managed care enrollment cut-off dates and the barriers, as well as potential solutions, to aligning Medicare and Medicaid managed care enrollment start and end dates. We solicited comment from interested parties, including States, D–SNPs, and Medicaid managed care plans, about their specific operational challenges related to

potential changes to Medicaid cut-off dates to align them with the Medicare start date. We also solicited comment on States' reasons for having a specific Medicaid managed care enrollment cut-off date in place.

We solicited comments on challenges individuals face when trying to enroll in integrated D–SNPs, as well as potential concerns stakeholders would have about CMS using flexibilities at section 1860D–1(b)(1)(B)(iv) of the Act and § 423.40(c) to determine effective dates for Medicare enrollments that occur in the context of our proposed special enrollment period for integrated care. We solicited comment on operational or systems barriers for States and Medicaid managed care plans to align disenrollment dates with Medicare. In addition to the above topics, we also solicited feedback on what type of technical assistance related to effectuating MA plan and D–SNP enrollment and eligibility processes would be helpful to States, what concerns should we consider about potential abusive enrollment practices, and on States' current requirements and policies related to agents and brokers. Finally, we solicited comments on whether other aspects of the integrated enrollment and disenrollment processes in FAI should apply to D–SNPs.

Comment: Several commenters believed that States have Medicaid managed care enrollment cut-off dates because of operational barriers. A commenter believed that cut-off dates allow for efficient planning and resource allocation, ensuring States can effectively manage and process a high volume of enrollments within a designated period. Some commenters expressed support for the idea of aligning Medicare and Medicaid enrollment effective dates, pointing out the challenges created by misaligned enrollment between D–SNPs and Medicaid managed care plans. However, most of these commenters cautioned that an approach would create substantial implementation challenges, including the need for system updates and training, as well as the potential for beneficiary confusion. Other commenters opposed the idea of aligning enrollment effective dates. A commenter did not believe this approach was feasible and believed it could harm consumers. Another commenter believed that if Medicare enrollment effective dates were aligned with Medicaid effective dates only in the context of AIPs, the commenter would be concerned about the added complexity this would create for organizations that operate additional D–SNP types (like coordination-only D–SNPs) alongside the AIPs. The commenter noted that having different enrollment effective dates for a subset of dually eligible individuals could also make it difficult for individuals to move seamlessly between D–SNP types when there are changes in eligibility.

Response: We thank the commenters for their input on these topics. While we are not responding to all specific comments submitted in response to this comment solicitation, we appreciate all of the comments and interest on these topics. These comments will inform our collaboration with States on D–SNP integration, and we will take them into consideration for potential future rulemaking.

I. Clarification of Restrictions on New Enrollment Into D–SNPs via State Medicaid Agency Contracts (SMACs) (§§ 422.52 and 422.60)

To elect a specialized MA plan for special needs individuals as defined at § 422.2 (special needs plans or SNPs), an individual must meet the eligibility requirements for the specific type of SNP in which the individual wishes to enroll. At § 422.52(b), we define the eligibility requirements for individuals to enroll in a SNP. These eligibility requirements indicate that an individual must meet the regulatory definition of a special needs individual at § 422.2, meet the eligibility requirements for the specific SNP they elect to enroll in, and be eligible to elect an MA plan under § 422.50. For D–SNPs, we also require at § 422.107(c)(2) that the categories and criteria for eligibility for dually eligible individuals to enroll in the SNP be included in the SMAC between the State and the D–SNP. D–SNPs must restrict enrollment eligibility categories or criteria consistent with the SMAC.

Currently, numerous States add eligibility categories and criteria to their SMACs that restrict new D–SNP enrollment to prioritize and promote integrated care. For example, some States only allow D–SNPs to enroll full-benefit dually eligible individuals. Other States only allow D–SNPs to enroll individuals who are also in an affiliated Medicaid managed care plan, creating exclusively aligned enrollment. State restrictions serve an important purpose in maximizing the number of dually eligible individuals who receive coordinated services through the same organization for both Medicare and Medicaid; minimizing disruption for enrollees currently served by existing D–SNPs; and allowing for the creation of D–SNP benefit packages that are tailored to certain subsets of dually eligible individuals.

State limitation of D–SNP enrollment to certain populations has been a feature throughout the history of D–SNPs. Nonetheless, we proposed regulatory amendments to further clarify our regulations.

We proposed to revise § 422.52(b)(2) to be explicit that to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC. We also proposed to revise § 422.60(a)(1) and add § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2). Neither proposal is intended to change our longstanding policy. We do not expect any new burden associated with these proposed changes because States are already including eligibility categories and criteria in their SMACs and we are reviewing those accordingly.

We received the following comments on this proposal and respond to them below:

Comment: Several commenters expressed support for our proposed revisions at §§ 422.52(b)(2) and 422.60(a)(1). In outlining their support, a commenter requested that CMS be cognizant of State Medicaid procurement practices, timeframes, and underlying State regulations and noted that compliance with new Federal requirements may take time given reprocurement timeframes, contract amendment processes, and State regulatory policies that may need to be updated. A commenter indicated that describing the intersection with Medicaid coverage and State Medicaid requirements in MA rulemaking is an important step toward improved clarity and alignment for integrated programs. In supporting CMS's proposed clarifications, another commenter encouraged CMS to better educate States on MA enrollment requirements to avoid the inclusion of enrollment restrictions within the SMAC that would put a D–SNP at odds with MA enrollment requirements. This commenter noted that many States have shared their limited expertise and capacity to manage complex D–SNP policies and additional technical assistance and education are needed.

Another commenter noted that it did not object to CMS's proposal to make explicit that, to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC.

Response: We appreciate the commenters' support for our proposed clarifications. CMS provides technical assistance to States on enrollment related topics, including through the

Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*), and we will consider these comments as our technical assistance approaches evolve.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment at § 422.52(b)(2) to be explicit that, to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC. We are also finalizing without modification our proposed amendment to § 422.60(a)(1) and addition at § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2).

J. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 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), we 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 [227] and subsequent years, as provided in § 422.514(d)(1), CMS does 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), and evidence-based models of care. In addition, we noted how limiting these D–SNP look-alikes would address beneficiary confusion stemming from potentially misleading marketing practices by brokers and agents that market D–SNP look-alikes to dually eligible individuals. 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 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 (85 FR 9018 through 9021) (also known as the February 2020 proposed rule).

In the April 2023 final rule, we finalized amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D–SNP look-alikes. Specifically, we finalized language at § 422.514(g) to apply the prohibitions on contracting with D–SNP look-alikes to individual segments of an MA plan. We also finalized language at § 422.514(d)(1) to apply the D–SNP look-alike contracting limitation to both new and existing (that is, renewing) MA plans that are not 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.

1. Reducing Threshold for Contract Limitation on D–SNP Look-Alikes

Our contracting limitations at § 422.514(d) mean that we do not contract with non-SNP MA plans that have enrollment consisting of 80 percent or more of enrollees who are entitled to Medicaid. We set the threshold at 80 percent or higher based on a 2019 MedPAC analysis that showed the proportion of dually eligible individuals in most geographic areas did not exceed the 80-percent threshold; [228] at that time, no MA plan service area had more than 50 percent dually eligible beneficiaries, and therefore dually eligible enrollment of 80 percent or greater would not be the result of any plan that had not intended to achieve high enrollment of dually eligible individuals (85 FR 33812). The 80-percent threshold also captured almost three-quarters of the non-SNP MA plans with more than 50 percent dually eligible enrollees (85 FR 33812).

In the June 2020 final rule, we stated that we would monitor for potential gaming after implementation of the final rule by reviewing plan enrollment data and consider future rulemaking as needed (85 FR 33812).

In response to our proposals to close unforeseen D–SNP look-alike loopholes in the April 2023 final rule, some commenters again recommended we lower the threshold to less than 80 percent (88 FR 22131). A few commenters recommended we lower the threshold below 80 percent without recommending a specific percentage, and other commenters recommended we lower the threshold to 50 percent. The commenters suggested that lowering the threshold further would promote integrated care and minimize beneficiary confusion. As one of these commenters, MACPAC noted that it ''remains concerned that while CMS's focus on plans where 80 percent or more of all enrollees are dually eligible addresses the most egregious instances, there could still be a real risk of growth in non-SNP MA plans falling below the 80-percent threshold and thus continuing to detract from Federal and State efforts to integrate care.'' We analyzed the percentage of non-SNP MA plans' dually eligible enrollment as a percentage of total enrollment from plan years 2017 through 2023. Our analysis shows that the number of non-SNP MA plans with high levels of dually eligible individuals has grown substantially.

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[227] We amended § 422.514(d)(1) in the April 2023 final rule, so the regulation text now refers to plan year 2024 and subsequent years; however, the regulation was in effect, with the reference to 2022 and subsequent years, as described here.

[228] See June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/impart_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

TABLE HJ1: TOTAL NUMBER OF NON-SNPS BY DUALLY ELIGIBLE INDIVIDUALS AS PERCENT OF TOTAL ENROLLMENT AND YEAR

Year	Total Number of Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	9	4	2	15
2018	13	6	5	24
2019	16	19	17	52
2020	30	18	17	65
2021	33	25	19	77
2022	58	35	26	119
2023	58	40	30	128
Percent growth from 2017 to 2023	544%	900%	1,400%	753%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023.

TABLE HJ2: TOTAL ENROLLMENT IN NON-SNP MA PLANS BY PERCENT OF DUALLY ELIGIBLE INDIVIDUALS ENROLLED AND YEAR

Year	Total Enrollees in Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	48,505	4,900	319	53,724
2018	49,367	4,180	3,737	57,284
2019	16,442	12,816	22,196	51,454
2020	85,320	24,281	28,019	137,620
2021	98,214	45,480	32,419	176,113
2022	137,380	70,348	35,313	243,041
2023	105,534	92,100	53,334	250,968
Percent growth from 2017 to 2023	118%	1,780%	16,619%	367%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023. This Table 2 reflects updates since the version of this table published in the November 2023 proposed rule, which only counted dually eligible enrollees in 2017 through 2022.

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The rate of growth from 2017 to 2023 in the number of non-SNP MA plans with 50 to 60 percent (544 percent increase), 60 to 70 percent (900 percent), and 70 to 80 percent dually eligible individuals as a percent of total enrollment (1,400 percent) [229] exceeded the rate of enrollment growth for all MA–PD plans (109 percent) over the same period of time.[230] The increased growth in non-SNP MA plans with dually eligible individuals between 50

[229] CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023, as shown in Table 1.

[230] CMS data from the Contract Year 2021 and 2023 Landscape Plan shows the total number of MA–PD plans in 2017 was 2,332 and the total number of MA–PD plans in 2023 is 4,875.

and 80 percent of total enrollment suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs, including requirements from the Bipartisan Budget Act of 2018, and detracting from Federal and State efforts to better integrate Medicare and Medicaid benefits. This growth in enrollment in these non-SNP plans is likely also drawing enrollment from integrated care D–SNPs and similar integrated programs. Recent analysis found that almost one-third of dually eligible individuals newly enrolled in D–SNP look-alikes were previously enrolled in fully integrated dual eligible SNPs (FIDE SNPs), other D–SNPs, PACE plans, or MMPs.[231]

We also conducted analysis with 2023 data mimicking MedPAC's 2019 analysis showing the share of dually eligible individuals enrolled in non-SNP MA plans against the share of beneficiaries in a plan service area who are dually eligible individuals.[232] MedPAC's analysis showed that in most MA markets, the share of beneficiaries in a plan service area who are dually eligible was clustered in the 10 to 25 percent range and in no county exceeded 50 percent. Their analysis showed that dually eligible individuals generally represented 30 percent or less of non-SNP MA plans' total enrollment. MedPAC's analysis informed our decision to set the threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeded the share of dually eligible individuals in any given market (by 30 percentage points or more) at that point in time and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. Similar to the earlier MedPAC analysis, our analysis of 2023 data shows the share of beneficiaries in a plan service area who are dually eligible is clustered in the 10 to 30 percent range and does not exceed 49 percent except in one county (at 56 percent).[233] Also like MedPAC, we found that for most non-SNP MA plans, dually eligible individuals generally represent 30 percent or less of the plan's total enrollment. However, whereas MedPAC found 13 non-SNP MA plans with dually eligible enrollment between 50 percent and 80 percent for 2017,[234] we found 128 non-SNP MA plans with enrollment in that range for 2023.[235]

To address the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals, we proposed lowering the D–SNP look-alike threshold from 80 percent to 60 percent incrementally over a two-year period. We proposed to lower the threshold for dually eligible enrollment to 60 percent of a non-SNP MA plan's enrollment because it exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area.

We proposed a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for contract year 2025. For contract year 2026, we proposed to reduce the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach would minimize disruptions to dually eligible individuals and allow MA organizations and CMS to operationalize these transitions over a two-year period. As discussed in more detail below, we would maintain processes to minimize disruption for the enrollees in plans affected by this proposed change.

Based on 2023 data, we stated in the November 2023 proposed rule that we expect the lower threshold would impact 30 non-SNP MA plans with dually eligible individuals representing 70 to 80 percent of total enrollment and 40 non-SNP MA plans with dually eligible individuals representing 60 to 70 percent of total enrollment. Some of the plans that could be affected by our proposal are offered in States (that is, California, Massachusetts, Minnesota) that limit contracting to integrated D–SNPs, such as FIDE SNPs and AIPs. Based on 2023 plan data, 12 non-SNP MA plans in California, Massachusetts, and Minnesota have shares of dually eligible enrollment between 60 and 80 percent. These States have chosen to limit their markets to certain D–SNPs to integrate Medicare and Medicaid for dually eligible individuals. Lowering the D–SNP look-alike contracting limitation to 60 percent will help to simplify choices for dually eligible individuals in these States and promote Medicare and Medicaid integration objectives.

We proposed revisions to the rule on dually eligible enrollment at § 422.514(d)(1) to apply the lower thresholds to new and existing non-SNP MA plan bids. Specifically, we proposed amending paragraph (d)(1)(ii) such that CMS would not enter into or renew a contract for a new or existing non-SNP MA plan that projects enrollment in its bid of 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; and 60 percent or more dually eligible individuals for plan year 2026 and subsequent years. Consistent with our current practice, we would apply the proposed changes at § 422.514(d)(1)(ii) to all bids for the next plan year, including any bids for non-SNP MA plans projected to exceed the threshold even if the actual enrollment for the current plan year is under the threshold at § 422.514(d)(1).

Similarly, we proposed revisions to paragraph (d)(2) to apply the lower thresholds to non-SNP MA plan enrollment. Specifically, we proposed to amend paragraph (d)(2)(ii) to state that we will not renew a contract with a non-SNP MA plan that has actual enrollment, using January enrollment of the current year, in which dually eligible individuals constitute 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; or 60 percent or more dually eligible individuals for plan year 2026 or subsequent years. In operationalizing these proposed changes, for example, we would use January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026. Consistent with existing rules, we would not apply the contracting limitation in § 422.514(d)(2) to any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals.

[231] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'' *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00193.*

[232] See June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

[233] CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

[234] June 2019 MedPAC Report to Congress, Chapter 12, calculated from Table 12–9 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

[235] CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

We solicited comments on whether an alternative to reduce the threshold to 50 percent is more appropriate to protect against plans circumventing the requirements for D–SNPs while enrolling a disproportionate number of dually eligible individuals.

2. Amending Transition Processes and Procedures for D–SNP Look-Alikes

Section 422.514(e) establishes parameters for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under the existing processes and procedures, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria. This transition process allows MA enrollees to be transitioned at the end of the year from one MA plan offered by an MA organization to another MA–PD plan (or plans) without having to complete an election form or otherwise indicate their enrollment choice as typically required, but it also permits the enrollee to make an affirmative choice for another MA plan or standalone Part D plan of his or her choosing during the annual election period (AEP) preceding the year for which the transition is effective. Consistent with our description of the transition process in the June 2020 final rule (85 FR 33816), if a transitioned enrollee elects to enroll in a different plan during the AEP, enrollment in the plan the enrollee selected would take precedence over the plan into which the MA organization transitioned the enrollee. Transitioned enrollees would also have additional opportunities to select another plan through the Medicare Advantage Open Enrollment Period described in § 422.62(a)(3) from January 1 through March 31. Affected individuals may also qualify for a SEP, depending on the circumstances.

Existing provisions at paragraphs (e)(1)(i) through (iv) outline specific criteria for any MA plan to receive enrollment through this transition process to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year. At existing paragraph (e)(1)(i), we allow a non-renewing D–SNP look-alike to transition that plan's enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than the threshold established in paragraph (d)(2)(ii) (now, 80 percent but with the proposed amendment, this would refer to the scheduled change in the threshold). SNPs receiving transitioned enrollment are not subject to this proposed limit on dually eligible individual enrollment. Under existing paragraph (e)(1)(ii), we require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Under existing paragraph (e)(1)(iii), any MA plan receiving transitioned enrollment from a D–SNP look-alike is required to have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a). Finally, paragraph (e)(1)(iv) requires that the receiving plan be of the same plan type (for example, HMO or PPO) of the D–SNP look-alike out of which enrollees are transitioned.

At existing paragraph (e)(2)(ii), the current transition process requires MA organizations to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the ANOC that the MA organization must send, consistent with § 422.111(a), (d), and (e) and § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the AEP.

At existing paragraph (e)(4), the regulation addresses situations where the prohibition on contracting or renewing a D–SNP look alike is applied and the D–SNP look alike is terminated. In such situations where an MA organization does not transition some or all current enrollees from a D–SNP look-alike to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), the MA organization is required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2).

This transition process is conceptually similar to ''crosswalk exception'' procedures at § 422.530(c). However, in contrast to the crosswalk exceptions, our transition process at § 422.514(e) permits transition across contracts and across MA organizations under the same parent organization, as well as from non-SNP plans to SNPs.

We proposed to apply the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the proposed D–SNP look-alike contracting limitation of 70 percent or more dually eligible individuals effective plan year 2025 and 60 percent or more dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D–SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures will help to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. However, for plan year 2027 and subsequent years, we proposed to limit the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Based on our experience with D–SNP look-alike transitions effective plan year 2023, the vast majority of enrollees are transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike. Based on our review of D–SNP look-alike transition plans thus far, we expect the experience for transitions effective plan year 2024 to follow a similar pattern. We proposed this new limitation on the transition process at new paragraph (e)(1)(v).

MA organizations can utilize other CMS processes to transition D–SNP look-alike enrollees to non-D–SNPs. For a more detailed discussion of these other CMS processes, we direct readers to the November 2023 proposed rule (88 FR 78582 through 78583).

While multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees from D–SNP look-alikes to D–SNPs. Consistent with the November 2023 proposed rule, we believe it is appropriate to limit the transition process in § 422.514(e) since although other options remain available to transition enrollees from the D–SNP look-alike, MA organizations do not have other options to transition D–SNP look-alike enrollees into D–SNPs, and movement into D–SNPs encourages enrollment in integrated plans. Furthermore, we are concerned that if D–SNP look-alikes continue to be allowed to transition enrollees into non-D–SNPs indefinitely, there is little incentive for MA organizations to avoid non-compliance with the D–SNP look-alike thresholds. Thus, for plan year 2027 and subsequent years, we proposed to add new paragraph § 422.514(e)(1)(v) to limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs.

We are solicited comment on an alternative to our proposal that would

eliminate the 70-percent threshold applying for plan year 2025 but would involve additional conditions and changes related to the transition authority Specifically, this alternative would:

- Apply the 60-percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond.

Relative to our proposal, this alternative would give plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment (based on January 2024 enrollment data) one additional year to apply for a new D–SNP or service area expansion to an existing D–SNP, such that these plans could transition enrollees into a D–SNP for plan year 2026. The alternative would balance the additional year using the existing 80-percent enrollment threshold to identify prohibited D–SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicited comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D–SNPs and to encourage and incentivize enrollment in integrated care plans. Among the factors we that stated that we would consider in adopting the alternative instead of our proposal is the extent to which plans with between 70 and 80 percent dually eligible enrollment in plan year 2024 expect to be able to establish a D–SNP in the same service area as the D–SNP look-alike if given an additional year (that is, 2026) to transition enrollees.

We also proposed a technical edit at § 422.514(e)(1)(i) to make the term ''specialized MA plan for special needs individuals'' lowercase, consistent with the definition of D–SNPs at § 422.2.

We received the following comments on this proposal and respond to them below:

Comment: Numerous commenters, including MACPAC and MedPAC, supported the proposal overall to lower the threshold used to identify D–SNP look-alikes to 70 percent dually eligible individuals for plan year 2025 and 60 percent dually eligible individuals for plan year 2026 and subsequent years and limit the D–SNP look-alike transition pathway to D–SNPs starting in plan year 2027.

A number of commenters emphasized the importance of dually eligible individuals having access to integrated care and that the D–SNP look-alikes interfere with those efforts. MedPAC referenced their June 2018 and June 2019 reports that discussed D–SNP look-alikes and expressed concern that D–SNP look-alikes undermine efforts to develop integrated plans for dually eligible individuals by encouraging them to enroll instead in plans that provide many of the same extra benefits as D–SNPs but do not integrate Medicaid coverage. MACPAC articulated that D–SNP look-alikes act at cross purposes to State and Federal efforts to integrate care by drawing dually eligible individuals away from integrated products and avoiding the additional requirements that D–SNPs must meet. Other commenters conveyed similar points in favor of CMS's proposal; D–SNP look-alikes work against the promotion of Medicare and Medicaid integration for dually eligible individuals, thus inhibiting improvements in coordination of care and attracting dually eligible individuals away from coordinated plan options. Other commenters supported the CMS proposal because it would further incentivize the enrollment of dually eligible individuals into D–SNPs, which are specifically designed for the population. A commenter did not believe that D–SNP look-alikes were a widespread phenomenon across regions but characterized them as substantial barriers to coordination of care for individuals in those regions where they exist. Another commenter stated that D–SNP look-alikes place responsibility on an enrollee to navigate two separate delivery systems.

In outlining their support for CMS's proposal, a number of commenters noted that D–SNP look-alikes are designed to attract dually eligible individuals but are not subject to the same requirements as a D–SNP, such as the model of care, coordination of Medicare and Medicaid benefits, and requirements for enrollee advisory input, designed specifically for dually eligible individuals. A commenter indicated that the contracting standards for D–SNP look-alikes should be consistent with the requirements for D–SNPs.

A number of commenters based their support for the CMS proposal on the expectation that it would simplify choices for dually eligible individuals and reduce aggressive marketing of D–SNP look-alikes. A commenter stated that D–SNP look-alikes introduce another layer of complexity and confusion for dually eligible individuals when selecting their plans, while not providing the coordination necessary for their enrollees to navigate Medicare and Medicaid programs. Other commenters noted that the proposed additional contract limitations for D–SNP look-alikes would ultimately help reduce confusion over plan offerings. Another commenter shared anecdotal evidence that marketing of D–SNP look-alikes, especially in nursing facilities, is confusing to potential enrollees. The commenter noted that D–SNP look-alikes may use aggressive marketing tactics and have zero-premium plans with many supplemental benefits, and thus these plans can look like a good deal to individuals. A few commenters stated that dually eligible individuals are often the least informed about their health insurance and that MA organizations exploit these individuals with D–SNP look-alikes when they would qualify for a D–SNP, which provides more comprehensive coverage. In advocating its support for the CMS proposal, another commenter indicated it had assisted dually eligible individuals who were targeted by D–SNP look-alikes, many of whom experienced complications related to Medicaid payment and crossover billing issues. A commenter advocated that third-party marketing agencies should be banned from marketing to dually eligible individuals and State Medicaid programs should prohibit using the enrollee list from different products for sales and outreach within the same company.

Other commenters shared CMS's concerns regarding the rapid growth of non-SNP MA plans with high levels of dually eligible individuals. Referencing their review of MA bid data for 2020, MACPAC noted that enrollment in non-SNP MA plans with more than 50 percent projected dually eligible enrollment grew by 23.4 percent from 2019 to 2020, but enrollment in D–SNPs grew by 13.9 percent over the same period. MACPAC expressed concern that enrollment growth in D–SNP look-alikes exceeded that of D–SNPs because many States rely on D–SNPs aligned with Medicaid managed care plans to integrate care for dually eligible individuals. Another commenter suggested that CMS's proposal is an essential step toward directly addressing concerns over the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals. Another commenter indicated MA plans have continued to target dually eligible individuals by retaining enrollment just below 80 percent dually eligible enrollment.

A commenter indicated that CMS's phased approach would provide plans a

helpful ramp to carefully plan enrollee transitions. In addition, the commenter indicated that reducing the D–SNP look-alike threshold all at once could disrupt the marketplace and impact beneficiary coverage, which should be avoided.

Response: We appreciate the widespread support we received for our proposal to lower the D–SNP look-alike threshold over two years to 60 percent and to limit the D–SNP look-alike transition pathway to D–SNPs. Our proposal builds on the policies finalized in the June 2020 final rule to limit entering into or renewing contracts with non-SNP MA plans with high percentages of dually eligible enrollees and addresses the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals. We believe the lower thresholds and restriction on D–SNP look-alike transitions under § 422.514(e) that we are finalizing in this rule will enable us to more effectively implement Medicare-Medicaid integration requirements under the BBA of 2018 along with other State and Federal requirements. Our proposal will support 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 HRAs, and evidence-based models of care. We agree with the commenters that our proposal will simplify beneficiary choices, reduce beneficiary confusion stemming from potentially misleading marketing practices by brokers and agents that market D–SNP look-alikes to dually eligible individuals, and further promote enrollment in integrated care plans.

Comment: Numerous commenters supported the CMS proposal to lower the threshold and recommended that CMS lower the D–SNP look-alike threshold further below the proposed threshold of 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.

A number of commenters suggested lowering the D–SNP look-alike threshold to 50 percent. A few commenters emphasized that a 50-percent threshold would be a more effective threshold for deterring MA plans from soliciting dually eligible individuals into non-SNP MA plans and ensure plans are not designed to target dually eligible individuals and circumvent statutory requirements for D–SNPs. Another commenter recommended the D–SNP look-alike threshold be lowered in subsequent years to 50 percent, with further reductions considered as the plan landscape and D–SNP integration continue to shift. Another commenter opined that any plan where more than 50 percent of the enrollment is comprised of people who are dually eligible should be subject to the same additional requirements and oversight as D–SNPs to protect enrollees. In referencing a recent study,[236] a commenter noted that there were more dually eligible individuals enrolled in the non-SNP MA plans where 50 percent or more of enrollees are dually eligible than there were enrolled in FIDE SNPs in 2020, and county level availability of non-SNP MA plans where 50 percent or more of enrollees are dually eligible also increased dramatically, from just 75 counties (fewer than 3 percent of U.S. counties) in 2013 to 1,318 counties (more than 40 percent of U.S. counties) in 2020. The commenter suggested that these data support lowering the D–SNP look-alike threshold to 50 percent. Citing prior MedPAC analysis, MACPAC explained that it considers D–SNP look-alikes to be plans where more than 50 percent of enrollees are dually eligible.[237]

Several commenters suggested lowering the threshold to 40 percent. A commenter suggested that CMS lower the D–SNP look-alike threshold to 50 percent in plan year 2025 and 40 percent in plan year 2026 and subsequent years, noting that the lower thresholds would make it more difficult for an MA organization to create a PBP that could undermine Medicare-Medicaid integration. A commenter recommended that CMS reduce the D–SNP look-alike threshold to 40 percent by 2026, emphasizing that the establishment of D–SNP look-alikes does not appear to be unintentional because these plans are often in areas where their ratios of enrollees do not mirror the general population ratio and many of D–SNP look-alike enrollees were previously enrolled in integrated D–SNPs. The commenter further supported a reduction to 40 percent since D–SNP look-alike growth has continued despite CMS' previous efforts to curtail the growth in D–SNP look-alikes, and these plans seem to just come under the threshold CMS sets. Another commenter requested that CMS consider lowering the threshold to 40 percent by 2030.

A few other commenters recommended that CMS consider D–SNP look-alike thresholds below 70 percent in plan year 2025 and 60 percent in plan year 2026 and subsequent years but did not specify a percentage.

A commenter specifically noted that it did not support lowering the D–SNP look-alike threshold to 50 percent since plans at or near 50 percent dually eligible enrollment may reflect the distribution of eligibility in the service area which is outside of MA organization's control. The commenter emphasized that the plan may appeal to both dually and non-dually eligible individuals equally, indicating the plan is not intentionally designed to attract dually eligible enrollees while circumventing D–SNP requirements.

Response: We appreciate the commenters' perspectives and acknowledge the substantial growth in the number of non-SNP MA plans with dually eligible individuals comprising 50 to 60 percent of total enrollment. Similar to the earlier MedPAC analysis, our analysis of 2023 data shows the share of individuals in a plan service area who are dually eligible is clustered in the 10 to 30 percent range and does not exceed 49 percent except in one county (at 56 percent). However, we proposed to lower the threshold for dually eligible enrollment to 60 percent of a non-SNP MA plan's enrollment for plan year 2026 and subsequent years because 60 percent exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible individuals in its service area. For these reasons, we are finalizing our proposal to lower the D–SNP look-alike threshold at § 422.514(d) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years, as proposed. We will continue to monitor non-SNP MA plans below the 60-percent threshold for potential gaming after implementation of the final rule and consider future rulemaking, as needed.

Comment: Other commenters expressed general opposition to the CMS proposal to lower the D–SNP look-alike threshold from 80 percent to 60 percent over a two-year period and, for plan year 2027 and subsequent years, limit the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible

[236] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

[237] See June 2020 MACPAC Report to Congress on Medicaid and CHIP, Chapter 2 at *https://www.macpac.gov/publication/chapter-2-integrating-care-for-dually-eligible-beneficiaries-policy-issues-and-options* June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

enrollees into D–SNPs. Some of these commenters noted that certain States do not contract with D–SNPs that enroll partial-benefit dually eligible individuals, which could reduce plan choices and benefits available to these beneficiaries. A commenter highlighted that many States have an inadequate number of SNPs in rural areas. A commenter noted that partial-benefit dually eligible individuals have similar levels of medical and social needs as full-benefit dually eligible individuals but are not being given the same level of support in navigating their health care choices. A few of these commenters indicated that partial-benefit dually eligible beneficiaries would either need to enroll in a different MA plan or enroll in Traditional Medicare, where they would not receive care coordination or valuable supplemental benefits. A commenter identified Arizona and Illinois as States where partial-benefit dually eligible individuals would need to enroll in products that are often designed to be attractive to those aging into the Medicare program and have fewer clinical and/or socioeconomic needs. This commenter raised concern that partial-benefit dually eligible beneficiaries could receive lower overall benefits, as rebates that would have been used to offer them lower Medicare Part C cost sharing or improved supplemental benefits would instead be directed to Part D drug cost-sharing reductions that are duplicative with their Part D Extra Help to attract enough non-dually eligible individuals to enroll in the non-SNP MA plan. Another commenter stated that Massachusetts and New Jersey are States that limit D–SNP enrollment to full-benefit dually eligible individuals and non-SNP MA plans would be further incentivized not to enroll partial-benefit dually eligible individuals if the threshold were lowered. That commenter recommended that CMS work with Congress to mandate such States to require their D–SNPs to have a separate PBP for partial-benefit dually eligible individuals as Pennsylvania and Virginia have done. A commenter recommended that CMS consider additional enrollment options for partial-benefit dually eligible individuals, such as modifications to the proposed monthly SEP. Another commenter indicated that the CMS proposal would force plans to avoid enrolling select categories of dually eligible individuals in their non-SNP MA plans where no D–SNPs are available and could create a vacuum where some dually eligible individuals no longer receive the benefits of MA, including the defined cost-sharing amounts, D–SNP model of care, and supplemental benefits designed to support SDOH.

Response: We appreciate the commenters' perspectives but do not find them to be sufficiently persuasive to change our position.

We agree that partial-benefit dually eligible individuals can benefit from enrollment in D–SNPs. As we stated in the June 2020 final rule (85 FR 33811 through 33812), partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D–SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these individuals have greater social, functional, and health needs than non-dually eligible Medicare beneficiaries. States, through their contracts with D–SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D–SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the State. Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

Of course, partial-benefit dually eligible individuals cannot benefit from these features of the D–SNP program if the State Medicaid agency contract with the D–SNP (that is, the SMAC) excludes these individuals from enrollment, and we recognize that some States using managed care as a platform for integration exclude partial-benefit dually eligible individuals from D–SNPs and other managed care plans. While some States are using the D–SNP platform for integration only to allow full-benefit dually eligible individuals to enroll in D–SNPs, others allow partial-benefit dually eligible individuals to enroll in separate D–SNP plan benefit packages.

Based on 2024 plan data, D–SNPs are widely available with 547 coordination-only D–SNP PBPs offered across 39 States,[238] and 457 of these coordination-only D–SNPs allow enrollment of partial-benefit dually eligible individuals.[239] In 2021, 54 percent of dually eligible beneficiaries were enrolled in a D–SNP and the majority were enrolled in coordination-only-SNPs.[240] The number of States with D–SNPs limited to partial-benefit dually eligible individuals has grown over recent years. For contract year 2024, D–SNPs that only enroll partial-benefit dually eligible individuals existed in 19 States and the District of Columbia, which is up from 11 States and the District of Columbia for contract year 2023.[241] We continue to think, as we conveyed in the May 2020 final rule (85 FR 33812), that allowing D–SNP look-alikes to continue to enroll partial-benefit dually eligible individuals with no limit would discourage States from taking this approach. As we stated in the June 2020 final rule (85 FR 33809), section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs. We will continue to work with States to identify ways to integrate Medicare and Medicaid benefits in a way that best serves the States' dually eligible population.

As discussed in the November 2023 proposed rule (88 FR 78600), most of the non-SNP MA plans with dually eligible enrollment between 60 percent and 80 percent of total enrollment have a D–SNP within the same service area or nearly the same service area as the non-SNP MA plans, providing a potential opportunity for transitioning D–SNP look-alike enrollees. We reviewed a sample of the 70 non-SNP MA plans with dually eligible individuals representing 60 to 79.9 percent of total enrollment (based on January 2023 enrollment data). While some of these non-SNP MA plans have services areas composed of a majority of Counties with Extreme Access Considerations, rural, and or/micro counties, most of the enrollment in the

[238] Integration Status for Contract Year 2024 D–SNPs available at: *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

[239] CMS analysis of contract year 2024 SMACs.

[240] MedPAC, State Medicaid Agency Contracts: Interviews with Key Stakeholders, January 25, 2024. Slides available at *https://www.macpac.gov/wp-content/uploads/2024/01/04_January-Slides_State-Medicaid-Agency-Contracts-SMACs_-Interviews-with-Key-Stakeholders.pdf.*

[241] States with partial-benefit only D–SNPs in CY 2024: Alabama, Connecticut, District of Columbia, Delaware, Florida, Georgia, Iowa, Idaho, Indiana, Kentucky, Maryland, Michigan, Mississippi, North Carolina, New York, Ohio, Tennessee, Virginia, Washington, and Wisconsin. States with partial-benefit only D–SNPs in CY 2023: Connecticut, District of Columbia, Delaware, Florida, Idaho, Michigan, Mississippi, New York, Ohio, Virginia, Washington, and Wisconsin.

sample we reviewed was is concentrated in urban areas.[242]

While coordination-only D–SNPs are widely available, we acknowledge they are not available in every market and there is potential that lowering the D–SNP look-alike threshold will result in some enrollees, including partial-benefit dually eligible individuals, not being able to transition into a D–SNP. Based on our experience with D–SNP look-alike transitions effective plan years 2023 and 2024 through MA organizations using the transition authority at § 422.514(e) or the crosswalk authority at § 422.530, in situations where the MA organization is not able to transition D–SNP look-alike enrollees into a D–SNP, the vast majority of enrollees transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike.

Comment: A commenter suggested that CMS's proposal might eliminate competition in the MA program for established D–SNPs and raised concern that these established D–SNPs might delay or avoid offering some additional benefits and instead increase provider payment or health plan profit margins.

Response: We acknowledge the commenter's concern. The D–SNP and MA markets remain robust. Plan bidding signaled strong interest in the D–SNP market for CY 2024, with the number of D–SNPs increasing by approximately 8 percent. Additionally, plans projected in their bids that MA enrollment overall is expected to grow over 7 percent, with D–SNPs enrollment expected to grow by approximately 13 percent.[243] Given that D–SNP look-alikes represent a relatively small share of MA–PDs overall, we do not expect our proposal to reduce the D–SNP look-alike threshold to 60 percent over two years and limit the D–SNP look-alike threshold pathway to D–SNPs starting in plan year 2027 to have a substantial impact on the competitiveness of the MA program.

Comment: Numerous commenters, but far fewer than the number of commenters expressing strong support for CMS's proposal, suggested that CMS exclude partial-benefit dually eligible individuals when calculating the percent threshold at § 422.514(d). A few of these commenters stated that only full-benefit dually eligible individuals benefit from enrollment in a FIDE SNP or HIDE SNP available in their county of residence and emphasized that since FIDE SNPs and HIDE SNPs generally are not an enrollment option for partial-benefit dually eligible individuals, the threshold should exclude partial-benefit dually eligible enrollees. Some commenters noted that D–SNPs serving partial-benefit dually eligible individuals are less widely available, and some States do not contract with coordination-only D–SNPs at all, limiting beneficiary choice and meaningful access to benefits.

Recognizing that some States choose not to contract with D–SNPs enrolling partial-benefit dually eligible individuals, a few commenters suggested that CMS not count partial-benefit dually eligible individuals toward the threshold in States that exclude partial-benefit dually eligible individuals from enrolling in D–SNPs. A commenter indicated that some States, like Massachusetts, limit D–SNP enrollment to full-benefit dually eligible enrollment, which restricts Medicare options to Traditional Medicare and regular MA plans. MA plans designed to support low-income Medicare beneficiaries by offering zero-dollar premiums and supplemental benefits that support functional and social needs risk meeting or exceeding the D–SNP look-alike threshold.

A commenter found CMS's proposal unclear regarding which enrollees—full-benefit dually eligible individuals, partial-benefit dually eligible individuals, and/or LIS eligible individuals—would count toward the D–SNP look-alike threshold under the proposed rule and recommended that only full-benefit dually eligible individuals be counted.

A commenter urged CMS to exclude partial-benefit dually eligible individuals who are not QMBs from the calculation of the D–SNP look-alike threshold since these beneficiaries do not qualify for full Medicaid benefits. The commenter believed that CMS's proposal, if applied strictly and rapidly, could stifle health plan efforts to create plans for the partial-benefit dually eligible individuals who are not QMBs.

Response: We welcome the commenters' perspectives, but we do not find them to be persuasive enough to outweigh other considerations that motivated our proposal.

Coordination-only D–SNPs are widely available with 547 such plans offered across 39 States in contract year 2024.[244] Of these 547 coordination-only D–SNPs, 457 enroll partial-benefit dually eligible individuals.[245] Also, 19 States contract with D–SNPs that limit enrollment of partial-benefit dually eligible individuals in contract year 2024. Partial-benefit dually eligible individuals are enrolling in these plans in high volume.

We recognize that some of the MA plans that could be affected by our proposal to lower the D–SNP look-alike threshold are offered in States that do not contract with D–SNPs that enroll partial-benefit dually eligible individuals. Such States include Arizona, California, Idaho, Massachusetts, Minnesota, and New Jersey. Based on January 2023 enrollment data, only ten of the 70 non-SNP MA plans with 60 to 79.9 percent dually eligible enrollment exist in States that only contract with D–SNPs that enroll full-benefit dually eligible individuals. These include five non-SNP MA plans in Arizona, three non-SNP MA plans in Massachusetts, and one non-SNP MA plan each in Idaho and Minnesota. These data indicate that partial-benefit dually eligible individuals are not congregating in non-SNP MA plans at high rates and do not suggest a need to remove partial-benefit dually eligible individuals from the D–SNP look-alike threshold calculation. We will monitor enrollment of partial-benefit dually eligible individuals, especially in service areas where they are not eligible for D–SNPs, to gauge whether enrollment of partial-benefit dually eligible individuals is causing non-SNP MA plans to cross the D–SNP look-alike threshold.

We acknowledge that the benefits provided under a D–SNP look-alike can be helpful to partial-benefit dually eligible individuals who do not have a D–SNP available to them. As articulated in the June 2020 final rule (85 FR 33805 through 33806), in contrast to non-SNP MA plans, D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. However, because most dually eligible individuals are QMBs who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic

[242] CMS analysis of January 2023 enrollment data and 2023 Individual Plan Service Area Data retrieved from HPMS.

[243] CMS, 2025 Medicare Advantage and Part D Advance Notice Fact Sheet, January 31, 2024. Retrieved from: *https://www.cms.gov/newsroom/fact-sheets/2025-medicare-advantage-and-part-d-advance-notice-fact-sheet.*

[244] Integration Status for Contract Year 2024 D–SNPs available at: *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

[245] CMS analysis of contract year 2024 SMACs.

exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D–SNPs in terms of level of dually eligible enrollment and benefits and cost-sharing design, D–SNP look-alikes are regulated as non-SNP MA plans and are not subject to the Federal regulatory and State contracting requirements applicable to D–SNPs.

As we outlined earlier in this section and in the November 2023 proposed rule, the rate of growth in non-SNP MA plans with 60 to 70 percent and 70 to 80 percent dually eligible individuals as a percent of total enrollment exceeded the rate of enrollment growth for all MA–PD plans over the same period of time. The increased growth in non-SNP MA plans with such levels of dually eligible individuals suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs, including requirements from the Bipartisan Budget Act of 2018, and detracting from Federal and State efforts to better integrate Medicare and Medicaid benefits. This growth in enrollment in these non-SNP plans is likely also drawing enrollment from integrated care D–SNPs and similar integrated programs.[246]

Removing partial-benefit dually eligible individuals from the D–SNP look-alike threshold calculation would render our existing D–SNP look-alike policy less effective. For contract year 2023, only two of the 12 non-SNP MA plans that met the 80 percent threshold calculated based on all dually eligible individuals would have been identified as D–SNP look-alikes under the 80 percent threshold calculated with only full-benefit dually eligible individuals. For contract year 2022, 31 of the 47 non-SNP MA plans that met the 80 percent threshold calculated based on all dually eligible individuals would have been identified as D–SNP look-alikes under the 80 percent threshold calculated with only full-benefit dually eligible individuals. Of these 31 plans, 26 were in California, which has very few partial-benefit dually eligible individuals. Of the estimated 70 non-SNP MA plans with dually eligible enrollment of 60 percent to 79.9 percent that would be affected by our proposal, only 10 of those plans have full-benefit dually eligible individuals comprising 60 to 79.9 percent of their total enrollment. Changing the D–SNP look-alike threshold calculation to only include full-benefit dually eligible individuals would allow 60 of these non-SNP MA plans to continue, reducing the ability of CMS and States to meaningfully implement the BBA of 2018 requirements.

Consistent with our position articulated in the June 2020 final rule (85 FR 33811), our proposed regulatory language uses the terminology from section 1859(f) of the Act and in § 422.2 to define the population of special needs individuals that D–SNPs may exclusively enroll. This language includes both full- and partial-benefit dually eligible individuals. Exclusion of partial-benefit dually eligible individuals from the threshold would allow any MA organization to design a benefit package and target enrollment for an MA plan that exclusively enrolled partial-benefit dually eligible individuals. Section 1859 of the Act, however, only allows D–SNPs to exclusively enroll dually eligible individuals.

We appreciate the commenters' suggestions for CMS to encourage States to contract with D–SNPs that enroll partial-benefit dually eligible individuals. We reiterate that section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs in their State using the SMAC. Nonetheless, the number of partial-benefit-only D–SNPs is increasing, and we will provide technical assistance to States interested in developing SMACs for such plans.

Comment: A commenter requested that CMS consider setting different dually eligible enrollment thresholds for full-benefit and partial-benefit dually eligible enrollees. The commenter suggested such thresholds could be consistent nationwide for both groups, a threshold determined by the percentage of full-benefit and partial-benefit dually eligible beneficiaries in a State, or a threshold that accounts for whether partial-benefit dually eligible beneficiaries can enroll in D–SNPs in the State. The commenter advised that this would allow CMS to set a lower threshold for full-benefit dually eligible beneficiaries and encourage their enrollment into integrated D–SNPs while allowing a higher percentage of partial-benefit dually eligible beneficiaries to remain enrolled in their plan. Another commenter recommended that CMS remove from the calculation of the percent threshold at § 422.514(d) any dual eligibility category for which D–SNPs are not available in the service area. The commenter indicated that as the D–SNP landscape becomes more complicated, the threshold calculation should incorporate additional nuances to avoid penalizing non-SNP MA plans for enrolling dually eligible individuals when there are not suitable D–SNP options available for every eligibility type.

Response: We appreciate the suggestions although we are not incorporating them into the final regulation. For the reasons articulated elsewhere in this section in response to comments suggesting that we limit the D–SNP look-alike calculation to full-benefit dually eligible individuals, we are retaining the current approach of using both full-benefit and partial-benefit dually eligible individuals in determining which non-SNP MA plans meet the D–SNP look-alike threshold at § 422.514(d). The other suggested approach would require CMS to calculate D–SNP look-alike thresholds specific to each county given the type of D–SNPs offered, and which dually eligible individuals they enroll could differ from one county to another within a State. In addition to the reasons articulated in response to comments recommending that we limit the D–SNP look-alike threshold calculation to full-benefit dually eligible individuals, we believe it would be challenging for CMS to operationalize a policy that requires county-specific D–SNP look-alike threshold. We also believe a more complicated D–SNP look-alike threshold would require data analysis that could be less transparent and more challenging for MA organizations to replicate in making their business decisions about plan consolidations and bids.

Comment: A commenter requested that CMS consider changing the D–SNP look-alike definition in future rulemaking, noting that the current definition is overly broad and captures MA plans that are not intentionally enrolling large percentages of dually eligible individuals. The commenter opined that the high dually eligible enrollment in these plans is often due to the lack of plan options in an area, especially for partial-benefit dually eligible individuals for whom these plans provide robust benefits that they would not receive in Traditional Medicare. The commenter

[246] Ma, Y., Fakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

recommended that CMS consider updating the definition of D–SNP look-alikes to plans that exceed the dually eligible enrollment threshold and have a Part D basic premium set under the low-income premium subsidy amount as their only premium because such plans are structured to attract dually eligible individuals and draw them away from D–SNPs.

Another commenter suggested that defining D–SNP look-alikes solely based on the percentage of dually eligible enrollees promotes continued evasion, even after lowering the D–SNP look-alike threshold to 60 percent. As an example, that commenter indicated that MA organizations could increase the number of PBPs within a contract while enrolling slightly lower percentages of dually eligible individuals in each. To address this concern, the commenter suggested that CMS consider: 1) the D–SNP look-alike threshold is met when dually eligible individual penetration rates exceed the designated threshold at either the contract number or at the PBP level; and 2) revise the definition of D–SNP look-alikes to be plans that exceed—or that exceed by a certain amount—the average dually eligible individual penetration rate across non-SNP MA plans in each State. The comment provides the example that as of September 2023, approximately 14 percent of Massachusetts non-SNP MA enrollment came from full-benefit dually eligible individuals. A threshold set at even twice this Statewide penetration rate would fall significantly below the 60-percent threshold CMS proposed for 2026. The commenter explained that since markets MA plan markets vary widely across the country, establishing a range based on Statewide averages for dually eligible individual penetration in non-SNP MA plans would more accurately identify outlier plans. The commenter suggested another alternative which would tie the D–SNP look-alike threshold to the percent of Medicare beneficiaries who are full-benefit dually eligible individuals in each State. The commenter noted that in Massachusetts, 25 percent of Medicare beneficiaries are full-benefit dually eligible individuals, and, of these, 15 percent of Massachusetts' full-benefit dually eligible individuals were enrolled in a non-SNP MA plan in September 2023.

Response: We thank the commenters for sharing these ideas but we are not incorporating them into the final regulation.

As we stated earlier in this section, D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. Because most dually eligible individuals are QMBs who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, or other full-benefit dually eligible individuals who are protected under 42 CFR 422.504(g)(1)(iii) from paying any in-network cost sharing when the State is responsible for paying such amounts, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Thus, we do not believe that adding an additional criterion to the D–SNP look-alike definition of having a Part D basic premium set under the low-income premium subsidy amount as their only premium would be helpful or necessary in identifying D–SNP look-alikes.

While we appreciate the commenter's suggestion to revise the D–SNP look-alike threshold based on contract, PBP, and State dually eligible individual penetration rates, we believe it would be challenging for CMS to operationalize a D–SNP look-alike threshold that requires different dually eligible individual penetration rate across non-SNP MA plans in each State. As articulated earlier in this section, we believe a more complicated D–SNP look-alike threshold would require data analysis that could be less transparent and more challenging for MA organizations to replicate in making their business decisions about plan consolidations and bids.

Comment: A few commenters recommended that CMS encourage States to allow D–SNPs that enroll partial-benefit dually eligible individuals and educate States on the benefits of D–SNPs for partial-benefit dually eligible individuals, especially if CMS does not exclude partial-benefit dually eligible individuals from the D–SNP look-alike threshold at § 422.514(d). A commenter emphasized that, while partial-benefit dually eligible individuals are ineligible for most Medicaid services, these individuals have similar clinical, functional, and social needs as full-benefit dually eligible individuals and can benefit from access to stronger care management models available in D–SNPs.

Response: We appreciate the comments. As we have articulated in the June 2020 final rule (85 FR 33811 through 33812), we agree that partial-benefit dually eligible individuals can benefit from D–SNPs. First, partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D–SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these individuals have greater social, functional, and health needs. States, through their contracts with D–SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D–SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the State. Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

We emphasize that nothing about the proposals would discourage States from contracting with D–SNPs that enroll partial-benefit dually eligible individuals. Section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs. Nonetheless, we will continue to provide technical assistance to States interested in establishing SMACs with D–SNPs that serve partial-benefit dually eligible individuals.

Comment: A commenter suggested that CMS increase the number of enrollees permitted in the exemption under the current rules that a non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals.

Response: The commenter is correct that the current requirements at § 422.514(d)(2)(ii) exempt any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination based on January enrollment. We explained in the June 2020 final rule (85 FR 33813) that an appropriate comparison for D–SNP look-alikes is the minimum enrollment threshold for low enrollment SNPs,

which is 100 enrollees for plans in existence for three or more years; CMS applies this threshold and other considerations to identify MA plans that are not viable independent plan options to terminate the plans under § 422.510(a)(4)(xv).[247] We codified a minimum enrollment standard of 200 in § 422.514 to allow some additional flexibility for initial enrollment patterns that may not be representative of the longer term enrollment pattern for the plan. Once the initial enrollment period has passed or the number of enrollees during that first year of operation exceeds 200 enrollees, we continue to believe the enrollment profile accurately reflects whether or not the plan was design to exclusively enroll dually eligible individuals. We are not making any changes in response to this comment.

Comment: A commenter did not notice any limitation on the number of D–SNP look-alikes in a service area. Based on that observation, the commenter opined that MA organizations could offer more than one non-SNP MA plan in a service area and manage the level of dually eligible enrollment among these multiple plans such that none of them meets the D–SNP look-alike threshold, circumventing the policies to protect dually eligible individuals. This commenter recommended that CMS add additional language to limit MA plans in service areas where there are D–SNP options available, in service areas where D–SNPs are not an option, or in States where there are no D–SNPs, allowing dually eligible individuals to access supplemental benefits. Another commenter advocated that CMS provide States with the authority to prevent any MA organization from having D–SNP look-alikes, regardless of whether an MA organization offers D–SNPs in that State. A commenter recommended that the proposal should not apply in States that do not contract with D–SNPs and make that statement clearly in the rule.

Response: We appreciate the comments. We confirm that there is no current limitation on the number of non-SNP MA plans allowed in a service area. We will monitor the implementation of this final rule for unintended consequences or potential gaming by MA organizations.

As we stated in the November 2023 proposed rule (88 FR 78580 through 78581) and earlier in this section, the rate of growth from 2017 to 2023 in the number of non-SNP MA plans below the 80-percent D–SNP look-alike threshold substantially exceeded the rate of enrollment growth for all MA–PD plans over the same period of time. The increased growth in non-SNP MA plans with dually eligible individuals between 50 and 80 percent of total enrollment suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs. As a result, we are finalizing, as proposed, a reduction in the D–SNP look-alike threshold at § 422.514(d) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.

We clarify that the existing contracting limitations on D–SNP look-alikes at § 422.514(d) only apply in any State where there is a D–SNP or any other plan authorized by CMS to exclusively enroll individuals entitled to Medicaid, such as an MMP. This remains true despite the changes we are finalizing to the D–SNP look-alike threshold.

Comment: A commenter proposed that CMS limit further reductions to the D–SNP look-alike threshold calculation to States and counties where there exist at least eight integrated D–SNP offerings. The commenter explained that this approach would enhance choice and ensure States issue SMACs to qualified entities.

Response: We appreciate the importance of beneficiaries having enrollment options. As discussed in the November 2023 proposed rule (88 FR 78600), most of the non-SNP MA plans with dually eligible enrollment between 60 percent and 80 percent of total enrollment have a D–SNP within the same (or nearly the same) service area as the non-SNP MA plans, providing a potential opportunity for transitioning D–SNP look-alike enrollees. We also discussed earlier in this section that D–SNPs are widely available. Thus, we do not think it is necessary to limit further reductions in the D–SNP look-alike threshold to States and counties where there exist at least eight integrated D–SNP offerings.

Comment: A few commenters specifically signaled their support for the proposal to limit transition options available to identified D–SNP look-alikes. A commenter noted that eliminating the option to transition enrollees into traditional MA plans would immediately reduce incentives to transfer dually eligible individuals into an MA plan that in future years may reach the D–SNP look-alike threshold. A commenter expressed support for the proposal to limit the transition options, as the current scheme of allowing transition into non-D–SNPs does not provide any incentive for MA organizations to eliminate D–SNP look-alikes. Another commenter welcomed allowing D–SNP look-alike transitions only to D–SNPs since it would be a pathway of opportunity for partial-benefit dually eligible enrollment into coordination-only D–SNPs and bolster coordination-only D–SNPs as a conduit and platform for increased integration efforts with States.

Response: We appreciate the widespread support we received to limit transition options available to identified D–SNP look-alikes. We believe this amendment will support our goal to encourage the enrollment of dually eligible individuals into integrated plans. We acknowledge that not all States contract with D–SNPs that serve partial-benefit dually eligible individuals, and partial-benefit dually eligible individuals would not be eligible to transition to non-D–SNPs under the § 422.514(e) transition pathway starting with coverage for plan year 2027. In those situations, MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk processes.

Comment: Many commenters discussed their concerns about transitions of D–SNP look-alike enrollees into other plans. A few commenters noted that these transitions could cause potential disruptions in continuity of care among enrollees. Other commenters recommended that CMS continue the existing transition authority into non-SNP MA plans. Several commenters suggested that CMS continue to make existing crosswalk exceptions available to transition dually eligible individuals from D–SNP look-alikes into D–SNPs. In support of this approach, a commenter stated that CMS has regulations in place via the bid submissions process whereby plan crosswalking and consolidation does not negatively affect beneficiaries. Another commenter encouraged CMS to continue to permit the use of existing transition authority into non-SNP MA plans for plan years 2025 and 2026 to minimize beneficiary disruptions. That

[247] CMS has consistently used the 100 enrollee threshold for several years to identify low enrollment plans for termination under § 422.510(a)(4)(xv); see HPMS memo dated April 14, 2023, ''Final Contract Year (CY) 2024 Standards for Part C Benefits, Bid Review, and Evaluation,'' p. 4 (available online at *https://www.cms.gov/https/editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-2-april-10-14*) and Final CY 2020 Call Letter, available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

commenter stated that delaying the proposed change to limit transitions of D–SNP look-alike enrollees into only D–SNPs until plan year 2027 and beyond would grant MA organizations additional time to adjust to these changes and preserve beneficiary choice during that process, minimizing disruption for dually eligible enrollees that affirmatively selected their existing MA plans to meet their provider network and benefit preferences.

Response: We thank the commenters for their perspectives. We agree with the commenters that it is important to monitor for any gaps in coverage that may occur as enrollees are transitioned or crosswalked out of D–SNP look-alikes. The current process at § 422.514(e) allows D–SNP look-alikes to transition enrollees into an MA plan or plans meeting certain criteria within the same parent organization to promote continuity of care. Under our proposal and § 422.514(e) as finalized with the amendments we proposed, we continue these policies through plan year 2026, which will help provide continuity of care for individuals who are required to transition from D–SNP look-alikes under the initial years of implementing the lower thresholds. Based on our experience with D–SNP look-alike transitions effective plan years 2023 and 2024, MA organizations transition the vast majority of D–SNP look-alike enrollees into other MA–PDs under the same parent organization as the D–SNP look-alike, and the vast majority of the plans receiving these D–SNP look-alike enrollees are non-SNP MA plans. Thus, we do not expect limiting the § 422.514(e) transition pathway to D–SNPs beginning in 2027 to negatively affect the ability of MA organizations to transition D–SNP look-alike enrollees. Also, as we discussed in the November 2023 proposed rule (88 FR 78582 through 78583), MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk processes.

As we explained in the November 2023 proposed rule (88 FR 78583), while multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees from D–SNP look-alikes to D–SNPs. We believe it is appropriate to limit the transition process in § 422.514(e) to D–SNPs since MA organizations do not have other options to transition D–SNP look-alike enrollees into D–SNPs and movement into D–SNPs encourages enrollment in integrated plans. We are also concerned that if D–SNP look-alikes continue to be allowed to transition enrollees into non-D–SNPs indefinitely under § 422.514(e), there is little incentive for MA organizations to avoid non-compliance with the D–SNP look-alike thresholds. Thus, for plan year 2027 and subsequent years, we are finalizing our proposal to add new paragraph § 422.514(e)(1)(v) to limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs.

Comment: A commenter noted that the plan crosswalk examples outlined by CMS in the November 2023 proposed rule require the transition of all plan enrollees into a single plan or segments of a single plan and do not permit enrollees to be crosswalked to separate PBPs based on Medicaid eligibility, which could result in enrollee disruption. The commenter inquired whether CMS intended for MA organizations to use the transition process at § 422.514(e) concurrently with crosswalks permitted at § 422.530, and, if so, requested that CMS update the regulatory text accordingly and provide detailed implementation instructions through sub-regulatory guidance. Another commenter requested that CMS consider some specific transition options. These options included allowing dually eligible enrollees from the D–SNP look-alike to transition to another plan but allow non-dually eligible enrollees to remain in the D–SNP look-alike; allowing dually eligible enrollees who qualify for a C–SNP to transition to a C–SNP; and allowing dually eligible enrollees from the D–SNP look-alike to transition into D–SNPs and/or default to Traditional Medicare. Another commenter recommended that CMS consider allowing D–SNP look-alikes to convert into ''all dually eligible plans'' and crosswalk any non-dually eligible enrollees into other MA plans. A commenter also encouraged CMS to automatically approve crosswalk exceptions that were previously approved by CMS as part of the D–SNP look-alike transition proposal process.

Response: We welcome the comments and appreciate the opportunity to clarify our proposal. Under our proposal, MA organizations with non-SNP MA plans meeting the 70 percent D–SNP look-alike threshold for plan year 2025 or 60 percent D–SNP look-alike threshold for plan year 2026 can use the existing D–SNP look-alike transition process at § 422.514(e), which allows transition of D–SNP look-alike enrollees to one or more MA plans, including a D–SNP, C–SNP, or I–SNP, if they meet eligibility criteria. This approach allows the D–SNP look-alikes meeting the lower threshold in the first years of implementation to transition enrollees under the existing D–SNP look-alike transition pathway at § 422.514(e) for 2026.

Our proposal limits the transition pathway to D–SNP look-alike enrollees transitioning into D–SNPs in plan year 2027 and future years. Thus, MA organizations have time to execute SMACs for new D–SNPs in service areas where they anticipate their non-SNP MA plans may meet or exceed the revised D–SNP look-alike threshold at § 422.514(d). For D–SNP look-alike transitions in plan year 2027 and subsequent years, MA organizations could use the revised § 422.514(e) transition pathway to move eligible D–SNP look-alike enrollees into a D–SNP, and any remaining D–SNP look-alike enrollees would default into Traditional Medicare. Alternatively, MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk or crosswalk exception processes. We clarify that MA organizations cannot use the § 422.514(e) transition pathway concurrently with a crosswalk or crosswalk exception pathway at § 422.530.

Under the existing requirements at § 422.514(d)(2), we do not renew a contract with a D–SNP look-alike that meets or exceeds the 80-percent threshold. Thus, D–SNP look-alikes cannot retain any enrollment in the D–SNP look-alike. As we explained in the June 2020 and April 2023 final rules (85 FR 33812 and 88 FR 22130, respectively), 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, we will sever the D–SNP look-alike from the overall contract using our authority under § 422.503(e) to sever a specific MA plan from a contract and terminate the deemed contract for the D–SNP look-alike. This policy will remain in effect upon finalizing our proposals to reduce the D–SNP look-alike threshold to 60 percent over two years and limit the D–SNP look-alike transition process to D–SNPs starting in plan year 2027.

Under the existing provision at § 422.514(e), MA organizations can transition D–SNP look-alike enrollees into C–SNPs. The revisions we are

finalizing at § 422.514(e)(1)(v) will—for plan year 2027 and subsequent years—limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs. Thus, for plan year 2027 and subsequent years, MA organizations will not be able to transition D–SNP look-alike enrollees into C–SNPs.

We clarify that none of the D–SNP look-alike transitions previously approved under § 422.514(e) were automatically approved or confer any automatic approvals by CMS for future transitions under § 422.514(e). CMS reviews all D–SNP look-alike transitions to ensure they meet the regulatory requirements.

Comment: A few commenters suggested an inconsistency in CMS's proposals to lower the D–SNP look-alike threshold and limit the D–SNP look-alike transition pathway at § 422.514(e) to D–SNPs starting in plan year 2027. These commenters believed that the calculation of the D–SNP look-alike threshold would include both full-benefit and partial-benefit dually eligible individuals whereas CMS's proposed revisions to the D–SNP look-alike transition process would limit that transition process to full-benefit dually eligible individuals.

Response: We appreciate the opportunity to clarify our proposal. The commenters are correct that we include both full-benefit and partial-benefit dually eligible individuals in the calculation of the D–SNP look-alike threshold at § 422.514(d) and will continue that policy in the reduction to that threshold that we are finalizing in this rule. We clarify that our proposed limitation at § 422.514(e) on the D–SNP look-alike transition process starting in plan year 2027 would permit transition of full-benefit and partial-benefit dually eligible individuals from a D–SNP look-alike into a D–SNP, if those individuals meet the eligibility criteria for the receiving D–SNP and all requirements at § 422.514(e).

Comment: Several commenters suggested that more information be provided to dually eligible individuals to help them understand their enrollment options. A commenter recommended informing individuals when they enroll in a non-integrated model where an integrated model exists. The commenter explained that these disclosures would shift the education burden from the individual, where it sits today, to entities providing the coverage. Another commenter advocated that CMS require outlier or all non-SNP MA plans to regularly send notices and information to their dually eligible enrollees about the State's integrated and coordinated care options, including integrated D–SNPs and PACE plans, and such information could be defined in a CMS template and/or provided by the State Medicaid agency. The commenter also encouraged that CMS clarify in regulation and/or in sub-regulatory marketing guidance that MA organizations offering both non-SNP and D–SNP products must clearly identify the specific contract numbers and PBPs contracted in each State as D–SNPs on plan websites and in marketing materials as well as clearly disclose the States in which their Medicare plans do not operate as D–SNPs.

Another commenter suggested that the ANOC language sent to dually eligible enrollees being transitioned into another MA plan should be plain and straightforward and include contact information for SHIPs.

Response: We appreciate recommendations for improved education on the availability and benefits of integrated products. Under the requirements at § 422.111(a)(2), an MA organization must disclose information specified in § 422.111(b), which includes service area, benefits, supplemental benefits, and other information, in a clear, accurate, and standardized form. This § 422.111(b) requirement applies to ANOCs. We also require that MA plans include the contact information for SHIPs in all ANOCs. We appreciate the other recommendations for improved education on the availability of integrated plans. We will consider ways to strengthen this information through future rulemaking and our current authority, such as by considering an update to the pre-enrollment checklist at § 422.2267(e)(4) to require that MA organizations inform enrollees about available integrated plan options.

Comment: A commenter requested information about the future of enrollees in D–SNP look-alikes and whether community-based organizations will maintain their service provision capabilities. The commenter expressed concern about the sustainability of the home health program if all providers became managed care organizations.

Response: We welcome the opportunity to respond to this comment. As we described earlier in this section, CMS will not renew a contract with a D–SNP look-alike, but that D–SNP look-alike can transition its enrollment to one or more MA plans using the D–SNP look-alike transition pathway at § 422.514(e) or crosswalk or crosswalk exception pathways at § 422.530, if requirements are met. MA plans, including D–SNPs, are widely available with 761 MA plan contracts with approximately 33 million total enrollees based on January 2024 data,[248] and we do not expect lowering the D–SNP look-alike threshold at § 422.514(d) and limiting the D–SNP look-alike transition pathway at § 422.514(e) to D–SNPs to have a substantial effect on the extent to which beneficiaries can enroll in MA or community-based organizations can contract with MA organizations.

Comment: A few commenters encouraged CMS to consider providing plans more time before implementing its proposal. A commenter noted that using January 2024 enrollment data to identify D–SNP look-alikes for plan year 2025 may be problematic for some plans given that CMS would not finalize the rule until later in 2024. This commenter recommended that CMS implement the proposed reduction in the D–SNP look-alike threshold starting with plan year 2026, consistent with the June 2020 final rule in which CMS finalized the D–SNP look-alike threshold to begin two years later in 2022. Other commenters acknowledged that plans must secure State Medicaid agency contracts to offer D–SNPs, which can take several years depending on the State legislative framework and procurement schedules. Another commenter suggested that CMS consider allocating an extra one or two years for plans that reduce cost sharing by material amounts for Medicare covered services and have made a good faith effort to avoid D–SNP look-alike status but might also provide benefits such as non-emergency transportation, Part D co-pay reductions, and benefits that assist with housing, utilities, and food that appeal to individuals receiving Part D LIS and dually eligible individuals. Another recommended that CMS consider adding one-to-two standard deviations to the D–SNP look-alike thresholds, in addition to providing one-or-two extra years, to give start-up plans time to make adjustments.

Response: We acknowledge the commenters' requests that we consider a delay in lowering the D–SNP look-alike threshold but we do not find them persuasive. MA organizations have had opportunities to work with States to execute SMACs for new D–SNPs. In finalizing the existing contracting limitation on D–SNP look-alikes in the June 2020 final rule, we delayed implementation of the contracting

[248] CMS Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report—Monthly Summary Report (Data as of January 2024) retrieved from *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-01*.

limitation by one year from plan year 2022 to plan year 2023 but allowed MA organizations that volunteered to transition enrollees out of D–SNP look-alikes for plan years 2021 or 2022 to do so. Providing more time for implementation and application of the new contracting standard when it was first adopted was appropriate then to give MA organizations time to adjust. However, the D–SNP look-alike prohibition and contracting standard have been in place for several years at this point and MA organizations are familiar with it. We do not believe additional delay before implementing the lower threshold is necessary. Of the D–SNP look-alike enrollees that MA organizations voluntarily transitioned for plan years 2021 and 2022, more than 90 percent of these enrollees transitioned to D–SNPs. For D–SNP look-alikes that CMS would no longer contract with for plan years 2023 and 2024, MA organizations transitioned less than 30 percent of enrollees to D–SNPs, other SNPs, or MMPs. Despite having additional time to establish D–SNPs, these MA organizations did not establish new D–SNPs as the replacements for existing D–SNP look-alikes.

Since November 2023, MA organizations have been aware of our proposal to lower the D–SNP look-alike threshold to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. We explained in the November 2023 proposed rule (88 FR 78581) that in operationalizing the proposed changes, we would use January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We articulated that we would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026. Consistent with the existing rules, we will not apply the contracting limitation in § 422.514(d)(2) to any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals. Thus, MA organizations have had time to start working with State Medicaid agencies on SMACs, and they have additional time to continue to work with State Medicaid agencies after this rule is finalized and before contract year 2025 SMACs are due in July 2024.

With respect to new plans, the current requirements at § 422.514(d)(2)(ii) already exempt any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination based on January enrollment. As stated earlier in this section, once this initial enrollment period has passed, we continue to believe the enrollment profile accurately reflects whether or not the plan was designed to attract enrollment of dually eligible individuals.

For these reasons, we are finalizing the reduction in the D–SNP look-alike threshold as proposed without delay in implementation.

Comment: Several commenters, who all supported the CMS proposal, recommended that CMS continue to analyze and monitor D–SNP look-alikes. MACPAC urged continued rigor and analysis around D–SNP look-alike plan growth. Citing its April 2020 comments on the February 2020 proposed rule, MACPAC expressed support for CMS's efforts to restrict D–SNP look-alikes and encouraged CMS to pay particular attention to the set of plans where dually eligible beneficiaries account for between 50 and 80 percent of total enrollment. MACPAC also suggested that CMS monitor growth in enrollment of dually eligible beneficiaries in other types of SNPs, including C–SNPs and I–SNPs, and identify any potential effects on integration efforts. A commenter emphasized the need for CMS to continue to monitor and address potential loopholes in prohibiting D–SNP look-alikes. A commenter advocated that CMS monitor plans' actions and provide public information on compliance and enforcement with the D–SNP look-alike regulations. Another commenter noted that States have invested time and resources to implement, operate, and monitor integrated care models to better serve dually eligible individuals, and allowing sponsors to circumvent D–SNP requirements and oversight wastes Federal and State resources and dilutes the effectiveness of this work. To that end, the commenter suggested that CMS further collaborate with States, including sharing oversight responsibilities of the MA market with State regulators and proactively publicizing how to report concerns about misleading and potentially exploitative marketing behavior by agents and brokers. A commenter requested that CMS apply stronger penalties for MA plans that States, SHIPs, ombudsman programs, or dually eligible individuals identify as potentially misleading or exploitative marketing behavior.

Response: We agree with the commenters' concerns. As we have done since codifying the D–SNP look-alike contract limitations at § 422.514(d) in the June 2020 final rule, we will continue to monitor for potential gaming, review plan enrollment data, and consider future rulemaking as needed. We shared a list of the D–SNP look-alikes identified for plan years 2022 and 2023 and will post lists for subsequent years under ''Information about D–SNP Look-Alikes'' on the CMS website.[249]

We encourage stakeholders to contact 1–800-Medicare to report concerns about marketing behavior. We appreciate the suggestion that CMS share oversight responsibilities of the MA market with State regulators, but that issue is beyond the scope of this rulemaking.

Comment: A commenter recommended that CMS add new data reporting requirements to assist in monitoring non-SNP MA plans. In particular, the commenter encouraged CMS to require non-SNP MA plans to provide administrative data and encounters to States for their dually eligible enrollees, which would help State Medicaid agencies. The commenter noted these data would also act as a counter incentive to MA organizations developing D–SNP look-alikes and targeting dually eligible individuals for enrollment to avoid D–SNP coordination and integration requirements. The commenter further suggested that CMS require MA organizations to consult with States on new applications and renewals for non-SNP MA plans that would exceed the monitoring threshold or that include benefit design that would likely be less attractive to non-dually eligible Medicare beneficiaries. Finally, the commenter advocated that CMS share detailed data with States on dually eligible enrollment in MA plans, including relative to total enrollment, to support State awareness and ability to monitor non-SNP MA plans.

Response: We appreciate the commenter's concerns and suggestions and will consider them for future action. The recommendation to require non-SNP MA plans to provide administrative data and encounter data directly to States would likely require additional rulemaking and is outside the scope of this proposal. Prior to implementation of new program-wide Part C reporting requirements (under OMB control number 0938–1054), we make them available to the public for review and comment in complying with

[249] *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

the standard PRA process, which includes publication of 60- and 30-day **Federal Register** notices. We will also consider sharing additional data with States on dually eligible enrollment in MA plans. As stated earlier in this section, we currently post annual lists of D–SNP look-alikes online.

Comment: In submitting comments about CMS's D–SNP look-alike proposal, a commenter indicated that an MA plan's Star Rating may be negatively impacted if an enrollee stays with the same parent organization but elects to enroll in a D–SNP, which better serves the enrollees' needs than a non-SNP MA plan. This commenter suggested that CMS include flexibilities to establish exclusion criteria for the Star Ratings measure monitoring disenrollment from the MA plan to exclude enrollees from the disenrollment calculation if they enroll in the MA organization's FIDE SNP.

Response: We thank the commenter for raising this issue. As we state in section VIII.F. of this rulemaking, we do not currently have evidence to suggest allowing dually eligible individuals the opportunity to enroll into integrated D–SNPs in any month would negatively impact Star Ratings; in fact, we have reason to believe that the totality of the SEP proposals may actually benefit integrated D–SNPs, such as FIDE SNPs, on Star Ratings, including the Members Choosing to Leave the Plan measure. In 2023, a study published in *Health Affairs* noted that nearly one-third of dually eligible individuals in ''D–SNP look-alike plans,'' were previously enrolled in integrated care programs.[250] Such D–SNP look-alikes would no longer be able to accept enrollments using the dual/LIS SEP with the changes we are finalizing in this rulemaking. The revised duals/LIS SEP that we are finalizing in this rulemaking will dramatically reduce the total array of options available outside of the AEP while the integrated SEP that we are finalizing in this rulemaking will allow full-benefit dually eligible individuals to enroll in integrated D–SNPs, which together may improve integrated D–SNP performance on measures such as Members Choosing to Leave the Plan. Further, in the CY 2025 Advance Notice, we discussed a non-substantive update to that measure to exclude any enrollment into a plan designated as an AIP from the numerator of this measure, which could address the commenter's concerns here if that measure update is finalized; under the non-substantive update, CMS would treat a change in enrollment to an AIP, including FIDE SNPs, from a non-integrated MA plan as an involuntary disenrollment.

As we described in the June 2020 final rule (85 FR 33817), the specifications for the Members Choosing to Leave the Plan Star Rating measure allow individuals transitioned because of a PBP termination to be excluded from the calculation of this Star Rating measure. The vast majority of D–SNP look-alike enrollees transitioned into another MA plan or plans, including a D–SNP, will be identified in MARx as disenrollment reason code 09, termination of a contract (CMS-initiated), or disenrollment reason code 72, disenrollment due to a plan-submitted rollover. Neither disenrollment reason code 72 nor 09 are counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. As described in the Collection of Information section of this rulemaking, based on our experience with D–SNP look-alike transitions through plan year 2024, we estimate that 14 percent of transitioned D–SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned. MARx will identify these transitions as disenrollment code 13, disenrollment because of enrollment into another plan, and these transactions will be counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. Since the measure specifications do not penalize a plan for *involuntary disenrollment* that may be caused by this rulemaking, we do not believe a change to the Star Rating measure specifications is warranted.

Comment: A commenter expressed opposition to CMS's D–SNP look-alike proposals by citing potentially contradictory policies related to the enrollment of dually eligible individuals in MA plans, specifically the interaction between the current and proposed D–SNP look-alike policies and the Health Equity Index (HEI). The commenter noted that under the HEI, an MA contract may be eligible for an increase in its Star Rating if the contract performs well on a set of measures for enrollees with social risk factors (SRFs), and CMS identifies enrollees with SRFs as those who are (i) dually eligible individuals or receive the Part D LIS, or (ii) are eligible for Medicare due to a disability. The commenter explained that a contract is eligible for the maximum reward if enrollment of beneficiaries with SRFs is greater than the median across all contracts and opined that setting such a threshold would likely create an incentive for MA organizations to enroll more dually eligible individuals into MA–PDs. In contrast, CMS proposed to disenroll dually eligible individuals from a non-SNP MA plan with dually eligible enrollment of at least 60 percent of total enrollment.

Response: We appreciate the commenter raising this concern. We agree that there is potential for countervailing incentives between our proposal to lower the D–SNP look-alike threshold and the HEI calculation of enrollees with SRFs, which includes dually eligible individuals. However, we believe lowering the D–SNP look-alike threshold to 60 percent will not interfere with the HEI reward. In calculations of the HEI using data from the 2023 and 2024 Star Ratings that we released via HPMS in December 2023, the median percentage of dually eligible, LIS, and disabled enrollees was 41.8 percent. This median percent is well below the thresholds we are finalizing at § 422.514(d), even as it counts non-dually eligible individuals who do not count toward the look-alike threshold.

Comment: A few commenters requested clarity on the data CMS uses to calculate dually eligible individuals as a percent of total enrollment to determine which non-SNP MA plans are D–SNP look-alikes and the timing of this calculation. A commenter sought clarification on when CMS uses projected enrollment versus actual enrollment. Another commenter stated that the MMR that CMS uses to calculate the percent of dually eligible individuals does not always have the most up-to-date information, which may result in an incorrect calculation of dually eligible enrollment. The commenter encouraged CMS to consider using real-time State data to assess this percentage instead of relying solely on the MMR. A commenter noted that CMS reviewing the percentage of dually eligible enrollment as of January 1 of a plan year is challenging for new PBPs and instead recommended that CMS review the percentage at the time of bid submission using May or June enrollment percentages to allow plans the opportunity to account for both OEP and age-in enrollments.

Response: We thank the commenters for the opportunity to clarify the data we use to calculate the D–SNP look-alike threshold at § 422.514(d) and related timing. As outlined in existing requirements at § 422.514(d)(1), we do not enter into or renew a contract for a non-SNP MA plan that projects in its

[250] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

bid under § 422.245 that 80 percent or more of the plan's total enrollment is comprised of dually eligible enrollees. Per § 422.514(d)(1)(ii), we use enrollment projections submitted by the MA organization as part of its bid to make that determination. To make these determinations, in June we review enrollment projections in bids submitted in June for the following plan year. For example, we reviewed enrollment projections in bids submitted in June 2023 for plan year 2024 to determine whether 80 percent or more of the plan's total projected enrollment is comprised of dually eligible enrollees. The proposal that we are finalizing in this rulemaking will lower the percent at § 422.514(d)(1)(ii) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. For example, we will review enrollment projections in bids submitted in June 2024 for plan year 2025 to determine whether 70 percent or more of the plan's total projected enrollment is comprised of dually eligible enrollees.

Per existing requirements at § 422.514(d)(2), we do not renew a contract for an MA plan that has *actual* enrollment consisting of 80 percent or more enrollees who are dually eligible, unless that MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination. Per § 422.514(d)(2)(ii), we use January enrollment of the current year to make that determination. The proposal that we are finalizing in this rulemaking will lower the percent at § 422.514(d)(2)(ii) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years but would continue to use *actual* enrollment as of January of the current year. For example, we will review January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026.

We currently obtain the January enrollment data through the February MMR, which reflects enrollment through early January. For example, we use the February 2024 MMR to reflect January 2024 enrollment in a non-SNP MA plan. We believe the MMR file accurately represents a plan's enrollment and includes necessary dually eligible status indicators. While we appreciate the suggestion to supplement the MMR data with real-time State data, we do not believe that the added benefit outweighs the operational complexity of obtaining such real-time data from States. We note that the MMR file is the data source that CMS currently uses to determine D–SNP look-alikes, but we may change the data source(s) as necessary to identify accurate and reliable information about January enrollment in plans. We will continue to assess the accuracy of the data we use to calculate the D–SNP look-alike threshold at § 422.514(d)(2)(ii), but we are not making any changes to the data or timing of these calculations in the final rule and are finalizing as proposed.

As discussed earlier in this section, we believe the exemption for an MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals (based on January enrollment data of the current year) provides a new plan sufficient start-up time before being subject to the contracting limitation at § 422.514(d)(2). We decline to change the timing for determining D–SNP look-alike status based on actual enrollment because we believe clarifying D–SNP look-alike status and use of the transition process may affect the ways in which MA organizations structure their plan benefit packages; making such determinations later in the year would make it impractical to complete the determinations and ensure plans' requests to use the transition process meet the requirements of § 422.514(e) before bids are due on the first Monday in June.

Comment: We only received a few comments on the alternative we described in the November 2023 proposed rule of eliminating the 70-percent threshold applying for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would apply the 60-percent threshold beginning in plan year 2026; permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond. Some of these commenters opposed the alternative consistent with their opposition to CMS's proposal to lower the D–SNP look-alike threshold and revise the D–SNP look-alike transition process. A commenter welcomed the alternative providing plans an additional year to apply for new D–SNPs or service area expansions for existing D–SNPs. Another commenter believed the additional time provided by the alternative would be unnecessary because MA organizations have had the opportunity to apply for a D–SNP when they applied for a D–SNP look-alike and did not.

Response: We thank the commenters for responding to our request for comments on an alternative proposal. Our alternative proposal would delay lowering the D–SNP look-alike threshold by one year—to plan year 2026 rather than plan year 2025, as proposed—but would apply the 60-percent threshold starting with plan year 2026 rather than the 70-percent threshold. The alternative would also limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond, which is one year earlier than our proposal.

Our reasons for not implementing the alternative are consistent with our reasons for not delaying implementation of our proposal. As we articulated earlier in this section, the D–SNP look-alike prohibition and contracting standard have been in place for several years at this point and MA organizations are familiar with it. We do not believe additional delay before implementing the lower threshold is necessary. We agree with the commenter about MA organizations having had time to apply for a D–SNP although—as discussed earlier in this section—we recognize that some States do not contract with D–SNPs that enroll partial-benefit dually eligible individuals. In our experience with implementation of the existing D–SNP look-alike prohibition and contracting standard, despite having additional time to establish D–SNPs MA organizations did not establish new D–SNPs as the replacements for existing D–SNP look-alikes. Since November 2023, MA organizations have been aware of our proposal to lower the D–SNP look-alike threshold to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. MA organizations have had time to start working with State Medicaid agencies on SMACs, and they have additional time to continue to work with State Medicaid agencies after this rule is finalized and before contract year 2025 SMACs are due in July 2024. We are not finalizing the alternative approach in this rulemaking.

Comment: A few commenters, while supportive of the changes proposed throughout the rule, noted that there is limited or mixed published research on whether or not enrollment in integrated care for dually eligible individuals leads to improved outcomes. A commenter expressed concern that the model of

integration may fall short of potential and fail to ultimately make meaningful change in health outcomes for enrollees.

Response: We appreciate the commenters' thoughts on the issue, and we look forward to more analysis on the experiences of dually eligible individuals. While there is limited published research on the benefits of integrated care for dually eligible beneficiaries, we find value in the published research that currently exists through MedPAC, MACPAC, and other research bodies. While many of these research papers note that evidence for integrated care is currently mixed, we share MedPAC's position of being ''supportive of integrated plans as a way to address the misaligned incentives between Medicare and Medicaid, improve care coordination, and improve outcomes for dual-eligible beneficiaries.'' [251] We will continue to monitor the growing body of research, as well as continue to carry out our own monitoring, regarding integrated care so that dually eligible individuals have access to seamless, high quality health care.

Comment: A commenter suggested that CMS consider excluding dually eligible individuals from enrolling in non-SNP MA plans, including by reassignment, when any of the Part C, Part D, or overall Star Ratings fall below average, which the commenter identified as 3.0. The commenter offered data specific to Massachusetts, citing that within the four non-SNP MA plans with the highest rates of dually eligible enrollment (as of February 2023), 69 percent of dually eligible individuals were enrolled in a plan that received 2024 Part C, Part D, and/or overall Star Ratings of 2.5 or less and 31 percent of dually eligible individuals were enrolled in a plan rated 4.0 or higher. To target additional monitoring or exclusion of non-SNP MA plans with stratified low Star Ratings for its dually eligible enrollees, the commenter urged CMS to review Star Rating data stratified by full-benefit dually eligible individuals versus other Medicare beneficiaries within non-SNP MA plans disproportionately serving dually eligible individuals.

Response: We thank the commenter for sharing these perspectives. The comments are outside the scope of this rulemaking, but we will consider them for future rulemaking.

Comment: A commenter recommended that CMS take steps to put C–SNPs into the category of D–SNP look-alikes. The commenter described C–SNPs as restrictive in the level of coordination and services they provide, which exemplifies C–SNPs acting more like D–SNP look-alikes than true SNPs.

Response: We appreciate the comment, but it is outside the scope of this rulemaking. As we stated in the June 2020 final rule (85 FR 33813), we excluded SNPs from evaluation against the prohibition on D–SNP look-alikes to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. Nonetheless, we will monitor enrollment in other types of SNPs to assess whether such plans are structured primarily to serve dually eligible enrollees without meeting D–SNP requirements.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to §§ 422.514(d)(1)(ii), 422.514(d)(2)(ii), and 422.514(e), as proposed.

K. For D–SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100(o))

MA organizations offer a range of health plan options including Medicare savings account (MSA) plans, private fee-for-service (PFFS) plans, preferred provider organizations (PPOs), health maintenance organizations (HMOs) and health maintenance organizations with point of services benefits (HMO/POS). (See § 422.4.) The most common health plan options are HMOs and PPOs. HMOs generally require enrollees to use network providers. PPOs have a network of providers but also pay for services delivered by providers not contracted with the MA organization as a network provider. PPOs can be attractive to Medicare beneficiaries who want a broader choice of providers than would be available through an HMO or who have a specific preferred provider, like a psychiatrist, who is not in network. MA organizations offer PPOs that are open to all Medicare beneficiaries as well as D–SNP PPOs that enroll only individuals dually eligible for Medicare and Medicaid.[252]

We noted in the proposed rule that enrollment in D–SNP PPOs has increased in recent years, rising to approximately 925,000 enrollees as of May 2023, accounting for about 17 percent of total D–SNP enrollment. D–SNP PPO enrollment has increased by 38 percent from May 2022 to May 2023.[253] Four national MA sponsors account for over 98 percent of D–SNP PPO enrollment.[254]

Like PPOs offered primarily to Medicare beneficiaries not entitled to Medicaid benefits, D–SNP PPOs generally have higher cost sharing for out-of-network services than for the same services obtained from network providers. For non-D–SNP PPOs, the higher out-of-network cost sharing is meant to incentivize use of in-network providers. In D–SNP PPOs, however, the large majority of enrollees are protected from being billed for covered Medicare services delivered by Medicare providers, including out-of-network providers. Instead, when these enrollees access services, either State Medicaid agencies pay the cost sharing or, if State payment of cost sharing is limited by a Medicaid rate for the service that is lower than the amount the D–SNP paid the provider, the provider must forego receipt of the cost sharing amounts.

Those cost sharing amounts for out-of-network services in D–SNP PPOs are often significantly higher than the cost sharing for the same services under original Medicare, including for physician services, Part B prescription drugs, DME, home health, dialysis, and stays in SNFs, acute and psychiatric inpatient hospitals.

This higher cost sharing for out-of-network services in D–SNP PPOs raises several concerns. First, when State Medicaid agencies pay the cost sharing for out-of-network services, these levels of cost sharing raise costs for State Medicaid programs.

Second, certain dually eligible enrollees, specifically full-benefit dually eligible enrollees who are not Qualified Medicare Beneficiaries (QMBs), are liable for cost sharing if they go out of network to providers not enrolled in Medicaid, as services from these providers are not covered by Medicaid unless the provider is enrolled in Medicaid.

Third, the higher out-of-network cost sharing disadvantages out-of-network safety net providers serving D–SNP PPO enrollees in States where limits established by Medicaid rates for the service result in no State payment of cost sharing.[255] A more detailed

[251] MedPAC, Congressional Request for Information on Dual-Eligible Beneficiaries, January 13, 2023. Retrieved from: *https://www.medpac.gov/wp-content/uploads/2023/01/01132023_DualEligibles_RFI_MedPAC_Comment_SEC_v2.pdf.*

[252] There are currently no D–SNP PFFS plans. MSA plans are prohibited from enrolling dually eligible individuals. HMO/POS plans have 1,423,000 enrollees as of July 2023.

[253] D–SNP PPO enrollment was at approximately 668,000 as if May 2023.

[254] The four sponsors are UnitedHealth Group (69 percent of national D–SNP PPO enrollment), Humana (23 percent), Centene (4 percent), and Elevance (2 percent).

[255] For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service

discussion of the impact of higher out-of-network cost sharing in D–SNP PPOs can be found in the November 2023 proposed rule beginning on page 88 FR 78584.

In addition to the potential impact of this cost sharing structure on States, safety net providers, and dually eligible individuals, we believe such higher cost sharing for out-of-network services may result in situations that are inconsistent with the policy goals underlying section 1852(a)(2) of the Act. Section 1852(a)(2)(A) of the Act describes how MA organizations can satisfy the requirement to cover Traditional Medicare services (that is, Part A and B benefits, with limited exceptions) under section 1852(a)(1)(A) when covered services are furnished by non-contracted (that is, out-of-network) providers. This statute provides that the MA organization has satisfied its coverage obligation for out-of-network services if the plan provides payment in an amount ''so that the sum of such payment and any cost sharing provided for under the plan is equal to at least the total dollar amount for payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).''

For a non-D–SNP PPO, in which the majority of plan enrollees must pay plan cost sharing, the total dollar amount for a service paid at the Medicare rate will equal the total dollar amount under parts A and B, even if the cost sharing exceeds the cost sharing under Traditional Medicare.

For a D–SNP PPO, however, the vast majority of plan enrollees are not liable for cost sharing for out-of-network services, just as they are not liable for such cost sharing under Traditional Medicare.[256] Therefore, whenever State Medicaid limits on payment of Medicare cost sharing result in no payment of cost sharing or payment of only a portion of cost sharing, the total dollar amount of payment received by the out-of-network provider for these covered services is less than the provider would collect under Traditional Medicare whenever the plan out-of-network cost sharing exceeds the cost sharing for those services under Traditional Medicare.

This lesser net out-of-network provider payment in a D–SNP PPO undermines the balance of obligations and benefits among MA organizations and Medicare providers that the statute creates to regulate out-of-network payments and beneficiary access for the MA program. While section 1852(a)(2)(A) of the Act requires the total dollar amount to be at least as much as would be authorized under Traditional Medicare, Medicare providers are required by sections 1852(k)(1) and 1866(a)(1)(O) of the Act to accept such amounts as payment in full. When a D–SNP PPO imposes cost sharing greater than Traditional Medicare and that cost sharing is unpaid by the State and uncollectable from the beneficiary, the MA organization has, in effect, failed to fulfill the spirit of its side of this statutory scheme and the providers are in effect forced to accept less than they would receive under Traditional Medicare if they agree to treat the D–SNP PPO enrollee.

In a D–SNP PPO, therefore, we are concerned that the combination of these issues results in a situation frustrating the underlying intent of section 1852(a)(2)(A) of the Act because, for services furnished to many (if not all) enrollees in the D–SNP PPO, the out-of-network provider potentially receives a total payment that is less than the total payment available under Traditional Medicare. To address these concerns, we proposed new limits on out-of-network cost sharing under D–SNP PPOs. We have authority under section 1856(b)(1) of the Act to establish standards for MA organizations and MA plans to carry out the MA statute (that is, Part C of Title XVIII of the Act) in addition to authority, under section 1857(e)(1) of the Act, to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program. Further, CMS is not obligated to accept any and every bid from an MA organization and is authorized to negotiate MA bids under section 1854(a)(5)(C) and (a)(6)(B) of the Act. We proposed regulatory amendments that would establish minimum standards for D–SNP PPO plans that are consistent with and necessary and appropriate for the MA program to address our concerns.

We proposed at § 422.100(o)(1) that an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan (that is, a D–SNP) cap out-of-network cost sharing for professional services at the cost sharing limits for such services established at § 422.100(f)(6) when such services are delivered in network starting in 2026. The term ''professional services'' as used here means the same thing as it does in existing § 422.100(f)(6)(iii) and includes but is not limited to primary care services, physician specialist services, partial hospitalization, and rehabilitation services. Under this proposal, a D–SNP PPO with a catastrophic limit set at the mandatory MOOP limit in 2026 and subsequent years must have cost sharing for a visit with an out-of-network psychiatrist or other specialist (that is, cost sharing subject to paragraph (f)(6)(iii)) that is capped at 30 percent coinsurance. If the catastrophic limit is set at the intermediate MOOP limit in 2026 and subsequent years, the coinsurance cap would be set at 40 percent. If the catastrophic limit is set at the lower MOOP limit in 2026 and subsequent years, the coinsurance cap would be 50 percent. Under our proposal, the rules in § 422.100(f)(6) and (j)(1) about how we assess that copayments that are actuarially equivalent to coinsurance would apply to new § 422.100(o) as well.

Our proposal at § 422.100(o)(1) also would require that cost sharing for out-of-network acute and psychiatric inpatient services be limited by the cost sharing caps under § 422.100(f)(6) that now apply only to in-network benefits. Using the same methodology to calculate comparable FFS cost sharing in § 422.100(f)(6)(iv), the cost sharing limit for a D–SNP PPO with a catastrophic limit set at the mandatory MOOP limit could not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario in an out-of-network inpatient or psychiatric hospital. For catastrophic limits equivalent to the intermediate and lower MOOP amounts, higher cost sharing for out-of-network cost sharing for inpatient and psychiatric stays could be charged as described at § 422.100(f)(6)(iv)(D)(*2*) and (*3*), respectively.

We also proposed at § 422.100(o)(2), by cross-referencing § 422.100(j)(1), that cost sharing for out-of-network services under D–SNP PPOs be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans. For a more detailed discussion of these proposed limitations, which apply to chemotherapy/radiation services, Part B drugs, renal dialysis, SNF care, home

is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment. This is often referred to as the ''lesser of'' policy. Under the ''lesser of'' policy, a state caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service.

[256] For more information on cost sharing protections applicable to dually eligible individuals, see: *https://www.cms.gov/medicare-medicaid-coordination/medicare-and-medicaid-coordination/medicare-medicaid-coordination-office/qmb.*

health and DME, please see 88 FR 78585.

For regional PPO D–SNPs, we proposed to exclude paragraph (j)(1)(i)(C)(*2*) and the last sentence of paragraph (j)(1)(i)(E) regarding overall actuarial equivalence requirements to avoid conflict with section 1852(a)(1)(B)(ii) of the Act.

We believe our proposed uniform application of out-of-network cost sharing limits for all PPO D–SNPs is the appropriate way to address our concerns about section 1852(a)(2)(A), the shifting of costs to States, the reduction in net payments to safety net providers, and the potential for excessive cost sharing for those dually eligible individuals, who, while low income, do not benefit from cost sharing protections out-of-network.

To provide the industry time to adjust to and for CMS to operationalize these new requirements, we proposed to implement these new limits starting for the 2026 plan year.

Currently, D–SNP PPOs already submit out-of-network benefits for a limited review to ensure that cost sharing does not exceed 50 percent of the costs (as required by § 422.100(f)(6)(i)) and in-network benefits for a review to ensure compliance with the cost sharing limits we propose to apply to out-of-network cost sharing. In the proposed rule (88 FR 78586), we stated that we do not believe this rule creates substantial information collection requirements. We received no comments on our burden estimates. In this final rule, we are finalizing, as proposed, that this rule does not create substantial information collection requirements.

In the proposed rule at 88 FR 78586, we discussed our burden estimate for this proposal, stating that we did not expect any new burden to be associated with these requirements. We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change.

We received the following comments on this proposal and respond to them below:

Comment: Numerous commenters, including the vast majority who commented on this topic, supported our proposal to impose limits on the out-of-network cost sharing for Parts A and B benefits in the benefit packages offered by D–SNP PPOs.

Response: We thank the commenters for their support.

Comment: A few commenters asked CMS to require the new cost sharing limits for plan year 2025 rather than for the 2026 plan year, as we had proposed.

Response: We decline to accelerate the timetable for implementation of this proposal. The additional time is necessary for changes to bid review systems and industry training on bid submission to enable implementation of the proposed requirements.

Comment: Several commenters supported the alternative proposal we had considered: capping all D–SNP PPO out-of-network cost sharing to levels consistent with Traditional Medicare. Several other commenters warned that imposing such limits, which are stricter than those imposed for in-network services, could result in an increase in cost sharing levels for in-network services.

Response: We appreciate the comments on the alternative we had considered in the proposed rule. We share the concerns raised from a variety of commenters on the potential to lead to higher in-network cost sharing and decline at this time to finalize these more stringent limits on out-of-network cost sharing for D–SNP PPOs.

Comment: MedPAC expressed support for policy remedies to address the cost sharing issues described in the proposed rule. However, citing CMS's finding that the cost sharing imposed by D–SNP PPOs is often higher than Traditional Medicare for out-of-network services and similar to Traditional Medicare for in-network services, MedPAC questioned how such plans are meeting the requirement that aggregate cost sharing be actuarially equivalent to the cost sharing charged under Traditional Medicare. MedPAC encouraged CMS to provide additional detail about how actuarial equivalence is assessed and enforced for D–SNP PPOs, and to provide evidence that the benefit packages of D–SNP PPOs charging high out-of-network cost sharing are meeting actuarial equivalence standards. MedPAC encouraged CMS to clarify whether cost sharing for in-network services can be reasonably expected to increase under the rule for plans seeking to maintain their current actuarial value and whether such an outcome is an intended consequence of the proposed policy.

Response: CMS regulations at §§ 422.100(f)(5) and 422.101(d)(3) require that all MA PPO plans have a maximum out-of-pocket (MOOP) amount. Because of the level of flexibility in these MOOP and cost sharing limit requirements, an MA plan could comply with the MOOP limit requirements, have cost sharing that is more generous on certain highly-utilized Part A or B benefits, and have cost sharing for other benefits that is higher than cost sharing in Original Medicare to design a benefit package that is actuarially equivalent to Original Medicare without offering reductions in cost sharing for Part A and B benefits as a supplemental benefit. However, most MA plans do offer supplemental benefits in the form of reductions in cost sharing for services under Parts A and B compared to Original Medicare. We consider the effect of the MOOP in evaluating the plan benefit packages for Medicare Parts A and B benefits to ensure actuarial equivalence. Where the MA organization's decision as to which MOOP level to use in combination with the other cost sharing requirements for basic benefits causes the basic benefit (that is, the Part A and B benefit package) to be actuarially more generous than Traditional Medicare, we treat that excess value as a mandatory supplemental benefit. Where an MA organization has elected to use cost sharing that is exactly like Original Medicare—where there is not a MOOP limit—for all Part A and Part B benefits, the MA organization has not balanced the actuarial value of the MOOP against other cost sharing in the MA plan to achieve a plan design that is actuarially equivalent to Original Medicare without any supplemental benefits. Using higher cost sharing for out-of-network services may provide a means to balance the actuarial value of the MOOP limit without resulting in the MA plan offering supplemental benefits in the form of cost sharing reductions for Part A and B benefits. Because the enrollees in a D–SNP PPO are generally protected from the cost sharing, the competitive incentives for a D–SNP to elect to offer cost sharing reductions as a supplemental benefit is reduced or eliminated in favor of the D–SNP covering additional items and services, which dually eligible individuals are more likely to perceive as more beneficial and useful.

Mathematically, under our final rule, the plan sponsor could increase the in-network cost sharing while decreasing the out-of-network cost sharing and still meet the actuarial equivalence requirements. However, there is a business disincentive associated with this action. If the in-network cost sharing were to increase, this could lead to lower payments for their network providers and future difficulties establishing networks. Therefore, we do not expect our proposed regulation limiting out-of-network cost sharing for D–SNP PPOs to increase in-network cost sharing.

In addition, section 1852(a)(1)(B)(ii) of the Act provides that in applying the requirement that MA plans cover Traditional Medicare benefits with

actuarially equivalent cost sharing does not apply to out-of-network services covered by MA regional plans; therefore, in evaluating whether the plan design—and cost sharing—of an MA regional plan complies with section 1852(a)(1)(B) of the Act, we do not consider out-of-network cost sharing. This is also reflected in § 422.100(j)(2), which excludes the out-of-network benefits covered by a regional MA plan from the cost sharing evaluations specified in § 422.100(j)(2)(i).

Comment: A few commenters expressed concern that the proposal would eliminate D–SNP PPOs which provide access to covered benefits outside of the plan's network while a few other commenters urged CMS to use its authority not to allow any D–SNP PPOs.

Response: We do not believe the requirements for increased cost sharing will force D–SNP PPOs to exit the markets. We note that, compared to non-D–SNP PPOs and to non-PPO D–SNPs, D–SNP PPOs had higher financial margins in the bids submitted for both the 2023 and 2024 plan years. And our final rule will not result in major changes to benefit design or other features that would cause disruption in the market. Not allowing any D–SNP PPOs is beyond the scope of this rulemaking.

Comment: Several commenters requested that CMS monitor the impact of finalizing and implementing the proposal, including on access to other supplemental benefits and on in-network cost sharing under D–SNP PPOs.

Response: We thank the commenters for this suggestion and will continue to monitor the offerings of D–SNP PPOs.

Comment: We received a number of comments that were beyond the scope of this rulemaking. These include several requests from commenters for CMS to improve access to in-network services, including for DME, teaching hospitals, and home care. A few commenters noted that the lesser-of policies employed by State Medicaid agencies can impede access to services for dually eligible individuals and disadvantage the providers who serve them. Several commenters noted that the materials used by D–SNP PPOs should provide an accurate picture of the cost sharing enrollees will face out-of-network. A few commenters requested that the proposed out-of-network cost sharing limits for D–SNP PPOs be applied to non-D–SNP PPOs as well.

Response: We thank the commenters for this input and will take it into consideration in our ongoing oversight of the MA program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendment at § 422.100(o)(1) that, starting in 2026, for an MA organization offering a local PPO plan or regional PPO plan, cost sharing for out-of-network services under D–SNP PPOs will be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans, as described in § 422.100(f)(6). We are also finalizing, with minor technical edits, our proposed amendment at § 422.100(o)(2) to limit out-of-network cost sharing to the cost sharing limits for such services established at § 422.100(j)(1) when such services are delivered in network by cross-referencing § 422.100(j)(1).

We also note that some of the public comments received for the provisions related to the integration of Medicare and Medicaid were outside of the scope of the proposed rule. These comments covered topics such as: opportunities for States to share in savings from integrated care and aligned enrollment; modernizing identification cards for dually eligible enrollees; impact of Medicare and Medicaid policies on rural areas; long term care pharmacy services for dually eligible enrollees eligible for institutional care; default enrollment; and private equity. We appreciate the input. However, as these comments are outside the scope of this rulemaking, they are not addressed in this final rule.

IX. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. PACE Past Performance (§§ 460.18 and 460.19)

Sections 1894(e)(4) and 1934(e)(4) of the Act establish CMS's authority to oversee the PACE program. To strengthen CMS's oversight of the PACE program, we proposed 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 will be a criterion CMS will use to review a PACE organization's application. The addition of this evaluation criterion at § 460.18(c) will permit CMS to deny applications from PACE organizations based on the organization's past performance. We also proposed to establish at § 460.18(d) that CMS may deny a PACE application if the PACE organization's agreement was terminated by CMS or not renewed during the 38 months preceding the date the application was first submitted to CMS.

The performance history of an organization is an important criterion for CMS to consider when evaluating a PACE application because the past performance of an organization may be a valuable predictor of an organization's ability to effectively operate a new PACE program or expand an existing program. Organizations that have performed well are more likely to continue their high performance while organizations that have not performed well may have even greater difficulty meeting regulatory requirements when operating a new or expanded PACE program in addition to their existing PACE program. CMS believes that adding the consideration of an organization's past performance will guard against poor-performing organizations expanding their footprint and putting the health and safety of future PACE participants they enroll at risk. It is important for CMS to ensure that the legal entities with whom we hold program agreements can safely, effectively, and appropriately provide health care services and benefits to PACE participants, who are frail and elderly and among the most vulnerable Medicare beneficiaries.

In the Medicare Advantage (MA) and Part D programs, CMS considers an organization's past performance during the evaluation of its application. We modeled the proposed PACE past performance review regulations after the MA and Part D past performance review regulations at 42 CFR parts 422 and 423, using applicable evaluation criteria. 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 initial and expansion applications of poorly performing organizations. As with its reviews of MA and Part D applications, CMS seeks through its review of PACE applications to identify poorly performing organizations and to prevent such organizations from entering into new agreements or expanding their service area in the program.

As explained in the proposed rule, 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 Part D regulations at 42 CFR part 423, except for those regulations CMS has waived in accordance with § 423.458(d). In addition, modeling after past performance reviews in MA and Part D reduces burden for PACE organizations 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 PACE entities that submit Part D applications.

In the January 2021 final rule (86 FR 5864), we 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 noncompliance 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, we adopted the following factors as the basis 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's threshold for compliance actions (*see* 86 FR 6000 and 87 FR 27704). Each of these factors, on its own, represents significant noncompliance 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.

In the December 2022 proposed rule, we proposed to apply a past performance methodology to entities that seek to offer a new PACE program or expand an existing program. We proposed to modify the PACE regulations at 42 CFR 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. Our proposed methodology for taking into account past performance when evaluating PACE applications is similar to the methodology we use 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 the proposed PACE past performance reviews is to prevent organizations from expanding their PACE operations in circumstances 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 the welfare of 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 discussed in the December proposed rule beginning on page 79637, we proposed that CMS would have the authority to 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. We did not propose to include Star Ratings in the past performance reviews for PACE because we do not calculate these measures for PACE organizations.

We accept applications on designated quarterly submission dates from entities seeking to either establish a PACE program or expand an existing program. Like 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, we approve the application.

We proposed 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 the statutory not-for-profit restriction no longer being applied beginning in May 2015, which allowed for-profit entities to operate PACE programs (see sections 1894(h) and 1934(h) of the Act).

From 2012 to 2013, Mathematica Policy Research, under contract with CMS, conducted a study to address the quality of and access to care for participants of for-profit PACE programs. Based on the 2012 Mathematica study and a prior study in 2008, HHS prepared and submitted the report to the Congress on May 19, 2015. Based on the findings in the report to Congress, we determined that under sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act, the requirement that a PACE program be a not-for profit entity would no longer apply after May 19, 2015 (the submission date of the report to Congress).

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 2022, we received 35 initial applications and 29 expansion applications. As of August 2023, there were 154 PACE organizations serving 70,209 participants in 32 States and the District of Columbia.

PACE participants are some of the most vulnerable Medicare beneficiaries. 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 chronic 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)).

As discussed in the proposed rule given the recent and anticipated future growth in PACE and the vulnerable populations that PACE organizations serve, we believe that the past performance of a PACE organization should be reviewed as part of the application process. Past performance evaluations ensure CMS only approves

initial PACE applications and applications for service area expansions from existing PACE organizations that have a strong and positive record of performance. 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 finalized rules 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's 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's 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. We proposed to use a 12-month review period for PACE past performance, which is the same lookback period that applies to MA and Part D past performance reviews. Under our proposal, CMS would review an organization's past performance for the 12 months preceding the deadline established by CMS for the submission of PACE applications. We proposed that, if CMS sends a Request for Additional Information (RAI) to the organization, the 12-month look-back review period would apply upon receipt of the applicant's response to CMS's RAI. As explained in the proposed rule, 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 proposed to specify at § 460.18(c)(1)(i) that CMS would evaluate the following components of an applicant organization's past performance, starting with the March 2025 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's proposed 13-point threshold for compliance actions with respect to the PACE program agreement. We proposed that, if any of those circumstances applies to the applicant organization, CMS may deny its initial or expansion application.

Specifically, we proposed 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 we may deny a PACE application, as noted in the previous paragraph. 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's regulations have either admitted they failed to comply with PACE requirements or have appealed and a third party has upheld CMS's determination that the PACE organization 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 proposed 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), we require 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 our evaluation of past performance because we have a responsibility to ensure the organizations that provide health care services to Medicare 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 its PACE physical site, leaving PACE participants without PACE access to their PACE organization. Based on this, we believe 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 proposed 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. Like an organization that lacks fiscal soundness, an organization that has filed for or currently is in State bankruptcy proceedings is at great risk of having insufficient funds to cover costs associated with administering 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, lack of care coordination, loss of access to providers (especially primary care providers who are employed by the PACE organization), and loss of the social and emotional support the PACE organization provides to participants. Thus, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the PACE program, and as CMS is responsible for oversight of PACE, we believe it is appropriate for us to have the authority to deny an application from any organization that has filed for or is in State bankruptcy proceedings.

Finally, we proposed 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. We proposed to specify at new § 460.19(a) that CMS may take compliance actions as described at § 460.19(c) (discussed in this section of this 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 at 42 CFR part 460. As proposed, § 460.19(a)(1) would provide that CMS may determine that a PACE organization is noncompliant 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, we proposed to establish at § 460.19(a)(2) 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, we issue three types of compliance actions: Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).[257] These actions are our 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 regarding how the organization intends to address the problem.

First, we proposed to specify that NONCs may be issued for any failure to comply with the requirements of the PACE organization's current or previously terminated program agreement. We typically use a NONC to document small or isolated compliance problems. NONCs represent the lowest level of compliance action issued by CMS. We typically issue NONCs for the least egregious failures, such as a first-time offense, a failure that affects only a small number or 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 marketing materials or incorrectly uploading these materials.

Second, we proposed to specify that a WL may be issued for a serious failure or continued failure to comply with the requirements of the PACE organization's current or previously terminated prior program agreement. WLs are typically issued as an intermediate level of compliance action and when discussing compliance actions on a continuum, would be issued for compliance issues that fall in terms of the level of their egregiousness between a NONC and a CAP. WLs are issued when an organization has already received a NONC and the problem continues to persist without correction, or they may be issued after a first offense when the offense concerns a larger or more concerning problem, such as failure to provide medically necessary services. Unlike NONCs, WLs contain language informing the PACE organization of the potential consequences to the organization should the non-compliant performance continue. An example of when a WL might be issued would be when, for example, a PACE organization has failed to have the full interdisciplinary team (IDT) involved in the review of participant care plans, which may result in participants not receiving necessary care. We might determine that the PACE organization's non-compliance in this regard warrants a higher level of compliance, such as a WL in place of a lower level of compliance. Our determination to issue a WL instead of a NONC, in this case, might be based on a review of factors, such as the type of care that was not received and the consequence of the care, not being properly provided, due to the PACE organization's failure to ensure that the IDT was reviewing all care plans.

Third, we proposed 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 non-compliance. We may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts participants. In these types of scenarios, we require the PACE organization to implement a CAP. The CAPs contemplated here 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 SAA through reviews and audits of the PACE organization (§ 460.194(a)(2)). We have a formal audit process, which separately identifies non-compliance. We issue CAPs under § 460.194(a)(2) resulting from finding of our reviews or audits. CMS routinely requests these CAPs and responses are submitted to CMS by PACE organizations as they address deficiencies identified during CMS reviews or audits. We expect to continue to request CAPs as necessary under § 460.194(a)(2) in response to deficiencies identified through reviews

[257] The CAPs we proposed 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.

or audits; nothing about this rule would change that process.

Consistent with the past performance methodology applicable to MA, we proposed to assign points to each type of compliance action taken by CMS against PACE organizations. We then proposed 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. We will then sum the total of the points accrued by the applicant organization, and if the total meets or exceeds 13 points during the 12-month review period, we may deny the organization's new or expansion application on the basis of past performance.

With the addition of compliance actions as a basis for the denial of applications, we proposed 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 proposed to codify in regulation the factors CMS currently uses when determining whether and at what level of a compliance action should be issued. As discussed in the paragraphs that follow, we consider 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.

We proposed to add § 460.19(b)(1) to establish that CMS considers the nature of the PACE organization's non-compliant conduct. The nature of the conduct is relevant to our 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.

We proposed to specify at § 460.19(b)(2) 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 our decision about the type of compliance action to take.

As 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 many or all of the 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.

At § 460.19(b)(4), we proposed to 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 for a period of time 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 regarding the PACE organization's previous failure to provide transportation, we may escalate this continued failure to comply with CMS requirements by issuing a WL, based on the PACE organization's history and continued failure to correct the deficiency.

As 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. We do not consider issues to be self-reported if they are identified through specific requests made by CMS, the review of data CMS either has or has requested, complaints that have come into CMS through sources such as 1–800–Medicare, or complaints that CMS has asked the PACE organization to provide. If an organization has self-reported a compliance issue, we may decide to lower the level of non-compliance (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, based on the factors identified previously, CMS determines that a higher-level compliance action is warranted.

Finally, we proposed to add § 460.19(b)(6) to provide that CMS considers the PACE organization's failure to adequately oversee its operations. For example, 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, we proposed to establish at § 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. We believe an organization whose performance results in issuance of two CAPs and a NONC, or whose performance results in any combination of compliance actions that adds up to 13 points, should not be permitted to expand.

We proposed to specify 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 our past performance methodology by establishing new legal entities and using those to submit PACE applications to avoid having CMS consider 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 we review 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, to consider information from the current or prior PACE program agreement(s) of the parent organization of the applicant, and from members of the same parent organization as the applicant. As noted in the proposed rule, we are seeing initial PACE applications more frequently that represent unique and distinct legal entities that are part of a broader parent organization. In the December 2022 proposed rule at page 79642, we described an instance in which 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 that case, in accordance with § 460.18(a) and (b), we 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. We denied the application due to the nature of the deficiencies that led to formal sanctions for the related organizations.

We also proposed one exception to this policy. Specifically, we proposed that 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 our requirements to acquire poorly performing PACE organizations without being penalized based solely on that acquisition. As stated in § 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 poorly performing organization.

Finally, we proposed 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 proposed 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, we 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 part 423, 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 our ability to terminate its PACE program agreement. Allowing organizations to re-enter the PACE program when they have failed to adequately implement a prior agreement would be contrary to 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.

We solicited comments on these proposals. We appreciate stakeholders' input on the proposed changes and have provided comment summaries and our responses later in this section.

Comment: Several commenters supported the evaluation of PACE organizations' past performance in CMS's application review process. Commenters also supported our proposed 24-month grace period and expressed appreciation for CMS's transparency in publicly sharing the past performance methodology.

Response: We thank those supporting the evaluation of past performance during application reviews.

Comment: A few commenters questioned whether the corrective actions resulting from CMS's audits are included in the calculation of compliance points. Commenters were concerned that issues identified in audits would unfairly disadvantage those organizations that have been audited by CMS within the past twelve months as compared to organizations that were not audited by CMS.

Response: We clarify that the compliance action plans identified in § 460.19(c)(3) are separate from the corrective action requests resulting from audits, as identified in § 460.194, and are not considered as part of the past performance methodology. We explained in the proposed rule that the corrective action requests resulting from audits are considered routine and result from a process which CMS considers

separate and distinct from past performance. We updated the language § 460.18(c)(1)(D)(*1*)(*i*) to state that these corrective action requests resulting from audits, as identified in § 460.194, are not issued points used for past performance evaluation purposes.

Comment: A few commenters were concerned that the 13-point compliance point threshold would disproportionately affect larger organizations. They expressed concern that organizations that had many center sites, especially in different States, could incur a disproportionate number of points due to the size or geographic spread of the organization.

Response: We do not believe that the compliance point threshold would disproportionately affect larger organizations because past performance is determined at the legal entity level, not the parent organization level. PACE organizations are generally licensed under different legal entities in each State. The compliance action taken against a contract only impacts that contract's legal entity and does not impact any other legal entity held by that parent organization. This eliminates the concern of the commenters that compliance actions will disproportionately affect larger organizations. Moreover, regardless of the size of the PACE organization, CMS expects all PACE organizations to comply with established requirements. Therefore, we decline to adjust the proposed 13-point calculation to account for the size of an organization.

Comment: A commenter requested that CMS outline the process, protocols, and compliance thresholds that rise to the levels of a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan.

Response: In the December 2022 proposed rule starting on page 79640, we outlined the factors CMS uses to determine whether to take a compliance action against a Medicare Advantage Organization and the level of compliance that is appropriate. The process CMS uses to determine whether to issue and how CMS issues a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan to an organization is the same for regardless of the type of compliance taken. CMS considers the following list of factors when determining the level of compliance action to take as described in this list, and we note that we may consider additional factors not specifically listed here that address the impact of the non-compliance or the organization's inadequate oversight that contributed to the non-compliance: the nature of the conduct, the degree of culpability of the organization, the actual or potential adverse effect on enrollees which resulted or could have resulted from the conduct of the organization, the history of prior offenses by the organization, the 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 the organization's inadequate oversight of the operations that contributed to the non-compliance. Once we determine the level of compliance action to issue based on our criteria, we issue the action to the organization through a letter. As for compliance review protocols, as discussed in the December 2022 proposed rule, we base the review protocols on the specific issue being reviewed in accordance with the approach detailed therein, for example, the standard protocol for fiscal soundness is such that the organization either has a positive or negative net worth. However, the protocols for other issues such as, for example, the failure to ensure enrollment packets are provided timely to participants are subject to review and consideration in accordance with the factors set forth at § 460.19, such as how many participants are affected and the lack of timeliness with respect to when the enrollment packets were actually received by an enrollee. Compliance thresholds may also be dependent upon specific circumstances. As identified above, compliance actions are taken for fiscal soundness if the organization has a negative net worth. The level of compliance taken for untimely delivery of an enrollment packet would depend on the application of the factors outlined in our final regulation. We believe these criteria and processes are well-documented in the December 2022 proposed rule and do not believe additional elaboration is needed here.

Comment: One commenter disagreed with our proposal to have the authority to deny an application based on past performance when an organization was under sanction, even though the sanction was ultimately lifted prior to CMS receiving the application. The commenter suggested that denying an application after a sanction is lifted would inhibit the expansion of PACE into new States.

Response: We believe sanctions, even if lifted, should be a basis for denial if that sanction was in place at any time during the twelve-month look-back period. A sanction is issued for serious non-compliance and is in place until such time the issue is corrected and not likely to reoccur. Sanctions issued for these reasons, indicate the organization should continue to focus on compliance rather than expansion, even after the sanction is lifted. We believe the inclusion of sanctions that have been lifted within the twelve-month look-back period is an important protection for the PACE program and the participants of the PACE organization that was under sanction as well as being consistent with Part C and Part D Past Performance regulations. For these reasons, we are finalizing our proposal to establish as a basis for denying a PACE application that an organization was under sanction within the twelve-month look-back period, without modification.

Comment: A commenter stated that CMS should not start the look-back period until 2025, noting that it would be unfair to use compliance letters issued prior to January 1, 2025. The commenter suggested that CMS exclude the time of performance during the COVID–19 pandemic and the associated public health emergency. This commenter also stated that CMS should provide PACE organizations time to train and educate employees on compliance.

Response: We understand the commenters concern regarding the time for consideration of compliance letters. By waiting, we could be providing PACE organizations additional time to correct any issues that might result in a compliance action. However, organizations should be vigilant about complying with program rules, regardless of the timing of the start of the past performance methodology. If a PACE organization is complying with CMS rules, the start of the period of past performance is immaterial. The timing is only a concern for those organizations whose current non-compliance would result in CMS denying an application based on past performance. It is exactly those organizations that should not expand and providing them with an additional year to come into compliance with existing rules is not in the best interest of the program or participants. This is particularly important should PACE organizations that are out of compliance attempt to expand during any period in which the start date of our consideration of past performance is delayed.

With respect to the commenter's contention that we should delay the implementation to avoid issues that may have resulted from the COVID–19 Public Health Emergency, we disagree. The federal COVID–19 Public Health Emergency declaration ended May 11, 2023, and sufficient time has passed allowing PACE organizations an

opportunity to address and cure any issues resulting from the Public Health Emergency and return to a normal state of operations.

Finally, the commenter suggested waiting so PACE organizations had time to train and educate their employees regarding past performance criteria. CMS's past performance measures do not require training or educating employees. Any training or educating would concern adhering to CMS regulations, which employees should already be trained on and educated about. Past performance only looks back at the actions of the organization and does not require the organization to do anything differently.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the rule as proposed.

Comment: A commenter suggested we use a six-month look-back instead of a 12-month look-back. The commenter stated that a 12-month look-back effectively prohibits an organization from expanding for 24 months.

Response: We do not believe a six-month look back is appropriate for a few reasons. The 12-month look-back period aligns with the look-back period used in the MA and Part D past performance methodology, which has proven effective over a number of years. In addition to aligning with the MA and Part D past performance methodology, we believe a 12-month look-back period allows for CMS to obtain sufficient data to determine whether an organization is operating in such a manner that we would deny an application. We believe a six-month look-back period is an insufficient amount of time for CMS to evaluate an organization's performance. We believe a 12-month look-back period is necessary to ensure an organization can provide the required services in a compliant manner over the long term, and not only in a shortened timeframe.

As mentioned previously, we are working towards consistency within programs and across programs where applicable. PACE organizations are already subject to Part D regulations. Establishing a 6-month look-back period for PACE would be inconsistent with the 12-month look-back period in the Part D regulations.

For these reasons, we are finalizing as proposed.

Comment: A few commenters stated that some PACE organizations may have high-quality programs but are not fiscally solvent and that applications from these organizations should be approved. A commenter stated that a PACE organization, to meet fiscal soundness requirements for expansion, may decrease staff or services resulting in less care for participants.

Response: We do not agree with the commenter that CMS should look beyond an organization's negative net worth when reviewing past performance. While a PACE organization may be able to provide quality services in the absence of a positive net worth, such an entity should not expand its operations until it demonstrates it can meet our fiscal soundness requirements. If such an organization were to expand operations the organization would likely incur additional costs, possibly resulting in further deterioration of the organization's fiscal soundness. An organization with a decreasing net worth and potentially experiencing cash flow problems, may reduce services to participants or the number of providers to continue operating, neither of which would be a desired outcome. As previously noted, we believe an organization's past performance is an indicator of future performance. We believe a positive net worth is critical to ensuring the future success of a PACE organization.

Based on these reasons we are finalizing these requirements as proposed.

B. PACE 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's authority regarding PACE provider application requirements. Based on this authority, we proposed 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 program's geographic service area and/or the addition of a new PACE center), on designated quarterly submission dates.

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 assurance document. The State assurance 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) and the designated agency for the PACE program in the State in which the program will be located. The document confirms the State's support for the PACE application. It is imperative that the applicant demonstrate the State's support of the application because the State is an equal party to the PACE program agreement, which, once approved and finalized, establishes the 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 an application received without the required State assurance 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 determine whether to approve or deny the application (§ 460.20(b)).

As part of annual training sessions and resources available at: *https://www.cms.gov/Medicare/Health-Plans/PACE/Overview,* CMS acknowledges and has stated that the State readiness review (SRR) of a center site, as applicable, is the only required application document that may not be available and submitted at the time of the initial application submission to CMS on the designated quarterly application submission date. The SRR is conducted at the applicant's PACE center by the State, and the accompanying report issued by the State certifies to the State and CMS that the PACE center satisfies all applicable local, State, and Federal requirements for operation. CMS has instructed PACE applicants to upload the SRR during the application process, including following the initial submission date if necessary, and when responding during the course of CMS's review to a CMS-initiated request for additional information from the applicant.

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 assurance 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 these aforementioned scenarios occur, CMS will instruct the applicant to withdraw the application.

In the December 2022 issue of the **Federal Register** (87 FR 79637) (hereinafter referred to as the December 2022 proposed rule), we proposed to treat any PACE application that does not include a signed and dated State assurance document, meaning a document with accurate service area information and the accurate physical address of the PACE center, as an incomplete and invalid application and therefore not subject to CMS review or consideration. Further, an application submitted without a valid State assurance document must be withdrawn from HPMS. These applicants must wait until the next quarterly submission date to submit the application with the State assurance document included. We proposed to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurance documentation is considered incomplete and invalid and will be removed from HPMS.

In the June 2019 final rule, we amended § 460.12(a) by adding the phrase ''in the form and manner specified by CMS'' to describe 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 (84 FR 25671) was issued. We proposed 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 it clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

In the December 2022 proposed rule, we proposed 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 assurance 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. We proposed § 460.20(b)(1) to 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. This is 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 proposed 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 42 CFR 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 submit a Part D application. Therefore, consistent with current practice, we did not propose to establish Part D application requirements for PACE organizations seeking to expand their existing service area. As stated in the proposed rule, we will 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 to promote consistency.

Consistent with current practice, we proposed 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. 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.

Comment: A few commenters were not in support of the State assurance form being a requirement for a PACE application submission. They requested that PACE applicants be afforded an opportunity to amend the State assurance document after application submission.

Response: We appreciate the comments and understand the request. The State assurance document is a necessary part of the application because the document demonstrates that the State is supportive of the PACE application. Since the State is a party to the 3-way agreement that is signed once the application is approved, it is important that the information provided on the State assurance form is correct at the time of application submission.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed requirements at §§ 460.12 and 460.20 to determine that a substantially incomplete PACE application without a State assurance document is a nonapplication. These provisions will strengthen the PACE regulations which pertain to application requirements, by further defining what constitutes a complete and valid application.

C. 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), we added § 460.64, which sets forth certain personnel qualification requirements for PACE staff. When drafting these regulations, we 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.*). We 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), we added § 460.71, which sets forth oversight requirements for PACE employees and contractors with direct patient care responsibilities. We 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, we 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.'' In the June 2019 final rule, we 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) to reduce confusion across PACE organizations.

The proposed rule at 87 FR 79643 discussed how we have seen as part of our audit and oversight activities that PACE organizations have an inconsistent approach to medical clearance. We further discussed how the COVID–19 pandemic impacted the population served by PACE and ''demonstrated a need for a more comprehensive approach to infectious disease management and prevention'' (*Id.*). 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. Therefore, we proposed 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 proposed 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 proposed 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 proposed 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. We proposed to include in paragraph (a)(6) language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date. As we discussed in the proposed rule at 87 FR 79644, CMS does not currently define what immunizations are included in the requirement that ''all immunizations are up to date.'' 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. However, based on the PACE population we also considered 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. We solicited 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, with particular focus on commenters' views on vaccinations recommended by ACIP. We also solicited 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 proposed 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. We solicited comment on adding this annual

requirement into the medical clearance provision.

We also proposed adding requirements to define what would constitute an acceptable medical clearance process. As discussed in the proposed rule at 87 FR 79644, 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 proposed 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; therefore, it would not be difficult to operationalize. We also proposed 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. We proposed 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.

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 proposed 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.

We proposed at § 460.64(a)(5)(iii) to establish the minimum requirements that the PACE organization must satisfy if it chooses to conduct a risk assessment for medical clearance. First, we proposed to 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. 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.

We proposed at § 460.64(a)(5)(iii)(B) to 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 we discussed in the proposed rule at 87 FR 79645, 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. We proposed at § 460.64(a)(5)(iii)(C) to establish a requirement 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 proposed 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 proposed 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, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, and Varicella Zoster Virus. We proposed 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 also proposed 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 or determines that a threat exists and communicates that threat via an official mechanism such as the CDC's Health Alert Network mentioned above. 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. As we discussed in the proposed rule at 87 FR 79645, 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. It is likely that any threat to public health related to communicable diseases would be shared through this mechanism, but we solicited 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 were not inclined to add a specific source into regulation, but we solicited comment on that as well. We also proposed 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. Although we 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 solicited 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. We discussed and accounted for the burden of updating the policies and procedures in the collection of information requirements section of the 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 proposed to amend the current language to state that all employees and contracted staff furnishing care directly to participants must be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5). We also proposed 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. Under our proposal, current paragraphs (b)(5) and (b)(6) would be redesignated as paragraphs (b)(6) and (b)(7). As we stated in the proposed rule, we believe that modifying this provision as proposed would not increase the burden on PACE organizations as they are already required to ensure employees and contractors have all immunizations up-to-date (87 FR 79646).

We received the following comments related to this proposal:

Comment: Several commenters expressed concerns with the solicitation for comment related to vaccinations. These same commenters noted that requiring an expansive list of required immunizations would create a new federal floor for PACE that was unlike what any other Medicare provider was required to adhere to. These commenters were concerned that requiring specific vaccinations would impair PACE organizations' ability to hire and retain staff. A commenter stated that a PACE organization had lost 30 percent of its staff after the COVID–19 vaccination rule went into effect. Another commenter requested that CMS clarify if religious and medical exemptions would apply to the new vaccination requirements. Multiple commenters requested that, if CMS finalized a list of required vaccinations, CMS finalize the more targeted subset of vaccinations for which CMS solicited comment, specifically Hepatitis B virus, influenza, measles, rubella, and varicella. Lastly, a commenter asked CMS to clarify whether the up-to-date COVID–19 requirement referred to the primary series or if booster shots would be required.

Response: When we issued the proposed rule (87 FR 79452) on December 27, 2022, many Medicare and Medicaid providers and suppliers (including PACE organizations) were required to have policies and procedures in place for staff vaccination against COVID–19. However, on June 5, 2023, we issued a final rule ''Medicare and Medicaid Programs: Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Diseases (ICFs-IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements'' (88 FR 36485), hereinafter referred to as the ''LTC 2023 final rule.'' In that final rule, we cited, among other considerations, ''increased vaccine uptake, declining infection and death rates, decreasing severity of disease, increased instances of infection-induced immunity'' as reasons for withdrawing the provisions of the COVID–19 staff vaccination rule (88 FR 36488). Taking these considerations into account, we removed the requirement at § 460.74(d) for PACE employees and contractors to be up-to-date with COVID–19 vaccinations. In our proposed rule, we had proposed referencing the COVID–19 vaccination rule at § 460.74(d) as part of our new paragraph § 460.64(a)(6). Following the withdrawal of that rule, we are not finalizing the proposed reference to § 460.74(d) in §§ 460.64(a)(6) and 460.71(b)(5).

We thank commenters for their concerns regarding PACE organizations' ability to staff due to the COVID–19 vaccination rule as well as our solicitation for comment relating to requiring a specific set of immunizations in the proposed rule. As we stated in the LTC 2023 final rule, ''[S]taffing shortages peaked nationally during the Omicron wave, with nearly one in three facilities reporting a shortage in January 2022. Staffing shortage rates have fallen since then, and remained relatively stable through March 2022, even after the implementation of the staff vaccination IFC'' (88 FR 36495). Based on the data available, we disagree with commenters that implementing additional vaccination requirements would adversely impact PACE organizations' ability to staff. However, we understand the concerns expressed by commenters that requiring a specific list of vaccinations for PACE organizations would potentially hold PACE organizations to a different standard regarding vaccinations than other Medicare programs. While we are not finalizing a specific list of vaccination requirements, and instead will leave the language in § 460.64(a)(6) that ''all immunizations must be up to date'', we will continue to assess the need for vaccinations. We will consider moving forward with a vaccination requirement in the future if the need arises. We also encourage PACE organizations to consider resources such as the ACIP vaccination standards when determining which immunizations to require for their employees and/or contractors.

Comment: Several commenters expressed concerns with the proposed requirement that medical clearance be conducted on an annual basis, versus only being done at the time of hire. These commenters suggested that it was overly burdensome for PACE organizations, particularly smaller organizations, to have to re-clear staff on an annual basis. These commenters also indicated that this would place an undue burden on a PACE organizations' ability to contract with other health care providers who may not be currently required to medically clear staff on an annual basis.

Response: We agree with commenters that an annual physical screening requirement may be overly burdensome for some PACE organizations since the requirement could impact PACE organizations' ability to contract with other health care providers. Therefore, we are not finalizing the proposed requirement that the physical examination or risk assessment be conducted annually. Instead, we will maintain the current requirement that direct care personnel be medically cleared prior to having direct contact with participants.

Comment: Most commenters requested that CMS codify the risk assessment approach to medical clearance as an alternative to requiring a physical examination for every individual. Commenters indicated this alternative proposal would allow PACE organizations to retain some discretion to medically clear staff as well as to reduce burden on PACE organizations. A couple of commenters requested that CMS leave medical screening requirements up to individual States, while a couple of other commenters expressed concern that home health agencies in certain States are not required to undergo additional medical screenings. These commenters noted

that State medical screening requirements apply to all health care providers within each respective State, and that requiring only PACE organizations to follow stricter federal requirements by conducting a physical exam in all instances or requiring specific vaccinations would put PACE organizations at a disadvantage when competing for contracts with medical providers and/or facilities. Instead, most commenters wanted CMS to finalize the risk assessment approach without requiring the PACE organization to conduct a physical exam.

Response: We thank commenters for sharing their concerns. We understand why commenters requested that we finalize the risk assessment alternative to the proposal that a physical exam be completed on each individual that provides direct participant care. As we stated in the proposed rule, PACE organizations serve a vulnerable population, and we believe performing a physical exam prior to staff having direct contact with participants is a best practice to protect participants from infectious diseases (87 FR 79644). However, we understand that requiring a physical exam for every individual that a PACE organization may employ or contract with may be overly burdensome, and therefore we proposed the risk assessment as a way for PACE organizations to determine if a physical exam is necessary for all personnel (*Id.*).

We recognize the concern commenters expressed of additional medical screening requirements putting PACE organizations at a disadvantage in contract negotiations with medical providers and/or facilities, including home health agencies, and as we discussed in our earlier responses, we are not finalizing our proposed requirements for annual medical clearance or a specific list of required vaccinations. We believe our decision not to finalize the annual physical screening requirement or the specific vaccination list will alleviate contracting concerns; however, PACE organizations can also take into consideration the processes they already have in place to demonstrate compliance with individual State requirements when they develop the risk assessment tool. Therefore, we are finalizing the requirement for a physical examination of direct care personnel with the risk assessment as an alternative provided the risk assessment meets the minimum requirements set forth in the proposed rule.

Comment: Multiple commenters raised questions and concerns regarding whether allowing colleagues to conduct health screenings would violate HIPAA. A commenter requested that PACE organizations be allowed to conduct physical exams or outsource them as needed. Another commenter asked that risk assessments without red flags be allowed to be reviewed by non-clinical staff to free up the time of clinical staff. A commenter supported CMS's approved list of clinical staff who can perform the risk assessment and/or physical exam.

Response: We appreciate the commenters' concerns over potential HIPAA Privacy Rule violations; however, we believe they are misplaced. The HIPAA Privacy Rule does not apply to employment records held by a covered entity in its role as an employer. In our experience, there are many medical organizations and hospital systems that perform medical clearance on personnel without violating the HIPAA Privacy Rule. However, it should be noted that the language allowing PACE organizations to perform their own physical exams or risk assessments was in no way meant to force PACE organizations to do so. Our intent was to allow PACE organizations the option to perform medical clearances in house; however, there is nothing in our proposal that would prohibit a PACE organization from requiring direct care personnel to seek a physical examination from their primary care physician or from contracting with a primary care provider for the specific purpose of conducting medical clearance reviews. As we stated in the proposed rule, we do not believe that assessments conducted by unlicensed staff or self-assessments are sufficient to meet the requirement for medical clearance (87 FR 79643). We also considered different clinical staff to determine the appropriate professions to perform the physical exam versus the risk assessment (87 FR 79645). We determined that while a physical exam required a primary care provider, a registered nurse could screen staff through the risk assessment because it is not ''a physical exam meant to diagnose an individual'' (*Id.*) We believe it is outside the scope of authority of nonclinical staff to perform a physical exam or risk assessment. Therefore, we are finalizing the clinical staff members approved to perform a physical exam or risk assessment, as proposed.

Comment: A commenter stated that the communicable disease clearance is a ''snapshot in time'' and is ineffective due to the transient nature of communicable disease. Another commenter stated that the proposal was not evidence-based, specifically the requirement to screen annually for Tuberculosis, which is not recommended by the CDC.

Response: We thank commenters for their responses. While screening for medical clearance prior to individuals having direct participant contact does not ensure that participants will never be exposed to communicable diseases, we believe it is a minimum safeguard to ensure that PACE participants are protected to the extent possible. It is also a common practice in other health care settings to have a process to ensure new individuals coming into an organization have received some form of health screening to demonstrate that the individuals are free of communicable diseases. As we stated in an earlier response, we are not finalizing the requirement for a physical examination or risk assessment to be conducted on an annual basis.

After considering the comments, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing the proposed changes to §§ 460.64(a) and 460.71(b)(4) in part, with a modification to remove the requirement to conduct medical clearance on an annual basis. We are finalizing the proposed changes to §§ 460.64(a)(6) and 460.71(b)(5) in part, with a modification to remove the reference to § 460.74.

D. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c))

As discussed in the December 2022 proposed rule, 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. Although the PACE regulations at 42 CFR part 460 have codified service delivery requirements established in the Act, they currently do not include specific timeframes for service delivery. Since the 1999 PACE interim final rule, in which CMS discussed the crucial role of timely comprehensive care and service delivery in maintaining participant functional status (64 FR 66251), we have continued to revisit the feasibility of implementing such timeframes in subsequent rulemaking (64 FR 66251, 71 FR 71292, 85 FR 9138, 86 FR 6034).

As discussed in the December 2022 proposed rule (87 FR 79648), previous rulemaking has highlighted the challenges of determining specific timeframes for delivering the varied and broad scope of services PACE organizations must provide to participants, which is further complicated by the many possible scenarios that are part of the multifaceted care needs of PACE participants. As required at the current § 460.98(b)(4), services must be provided as expeditiously as the participant's health condition requires. Determining how quickly a service must be provided would depend on more than the physical health of the participant, and PACE organizations must consider all aspects of the participant's condition, including their social, emotional, and medical needs when determining the provision of services. Although we continue to believe that a specific timeframe for service delivery would not be feasible, and that ultimately, a service delivery timeframe based on the needs of the participant's condition remains the best timeframe for service delivery, our monitoring and oversight efforts have demonstrated the need for additional participant protections regarding timely service delivery. For example, based on data collected through audits, in the past 4 years, over 80 percent of audited PACE organizations have been cited for a failure to provide services in a way that is necessary to meet participant needs.

In response to audit findings, in the December 2022 proposed rule (87 FR 79648), we proposed to strengthen participant protections and accountability for PACE organizations by amending the service delivery requirements at § 460.98 to establish maximum timeframes for arranging and scheduling IDT-approved services for PACE participants, allowing for certain exceptions. First, we proposed to amend § 460.98 by redesignating current paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively. Next, we proposed to add a new paragraph (c) with the heading ''Timeframes for arranging and providing services'' and add 4 new subparagraphs. In addition, we proposed to move the requirement in current paragraph § 460.98(b)(4) to new paragraph (c)(4). We also proposed to redesignate paragraph (b)(5) as (b)(4).

Our proposal at the new section § 460.98(c) included 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. We proposed 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 explained that 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 that would enable the pharmacy to fill the medication order and provide the participant with timely access to the medication. We explained that this timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery within that timeframe.

Next, we proposed 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 the 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 § 460.98(c)(3). This requirement pertains to all IDT-approved services other than medications. We would expect PACE organizations to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within the proposed timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. As with the proposal at § 460.98(c)(1), we noted that the proposed maximum timeframe to arrange or schedule the delivery of IDT-approved services, as we proposed at § 460.98(c)(2), does not apply a specific timeframe to the provision of the service.

We solicited comment on alternative maximum timeframes for arranging or scheduling IDT-approved services, particularly timeframes within 5 to 10 (that is, 5, 6, 7, 8, 9, or 10) calendar days after the date the IDT or a member of the IDT first approves the service. Additionally, we invited comment on whether there are additional definitions of ''arrange or schedule'' that we should consider. We requested that such comments address how the alternative timeframes they recommended would ensure participant health and safety, especially if commenters advocate for a timeframe longer than 7 calendar days.

We proposed at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of IDT-approved services. We proposed to specify at § 460.98(c)(2)(i)(A) that IDT-approved services include services approved by the full IDT. These services would typically be the ones discussed and approved during IDT meetings. This would be any service other than a medication. We proposed 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. We proposed at § 460.98(c)(2)(i)(C) that IDT-approved services include services ordered by a member of the IDT. We would consider an IDT member ordering a service as approving that service for purposes of proposed § 460.98(c)(2). We explained that, under our proposal at § 460.98(c)(2), the timeframe to arrange or schedule a service begins when the IDT or a member of the IDT first approves the service. Therefore, when any one of these approvals at § 460.98(c)(2)(i)(A) through (D) occurs, on that first instance, the timeframe would be initiated.

We proposed at new § 460.98(c)(3) to exclude routine or preventative services from the timeframe 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 a much later time. To satisfy this exception, we proposed 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 in § 460.98(c)(2). First, we proposed at § 460.98(c)(3)(i) that the PACE organization must document that it was unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of

the PACE organization. Second, we proposed to establish at § 460.98(c)(3)(ii) that the PACE organization is exempt from the timeframe as long as the participant does not have a change in status that requires the service to be provided more quickly. Last, we proposed 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.

We proposed to redesignate § 460.98(b)(4) as § 460.98(c)(4) without further modification, except to add a new paragraph heading ''Providing approved services''. Thus, 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. 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 estimated 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 these proposed timeframes for arranging and scheduling services in the Collection of Information Requirements section.

In the paragraphs that follow, we summarize the comments received on the proposal at § 460.98(b)(4) and (c) and respond to those comments.

Comment: A few commenters recommended that CMS address how PACE organizations would satisfy the proposed requirements at § 460.98(c) to ''arrange and schedule'' services. Specifically, two commenters recommended that CMS define ''arrange and schedule'' such that PACE organizations would demonstrate they have arranged and scheduled services when they can provide documentation that a service authorization was acted upon to initiate scheduling. Another commenter recommended that CMS add language to define ''reasonable efforts'', a term not included in the proposed provision, to arrange and schedule services with providers external to a PACE organization, particularly specialty providers. The commenter expressed concern that PACE organizations may be unfairly penalized for providers' communication delays that impact when provider appointments can be scheduled.

Response: We explained and provided examples of the actions a PACE organization would have to take to arrange and schedule services within the maximum timeframes at § 460.98(c) in the December 2022 proposed rule (87 FR 79649). The proposed rule explained that, for purposes of the proposed requirement at § 460.98(c)(1), we consider ''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 (87 FR 79649). This timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery in that timeframe. For the proposed requirement at § 460.98(c)(2), we described the action that we would expect the PACE organization to take within the proposed 7-calendar day maximum timeframe to arrange or schedule IDT-approved services other than medication (87 FR 79649). Delivery of services would not need to occur within the proposed timeframe, unless the participant's condition required delivery within that 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 (87 FR 79649). We also emphasized that, for our proposal at § 460.98(c)(2), the timeframe begins when the IDT or a member of the IDT first approves a service (87 FR 79650).

In the December 2022 proposed rule (87 FR 79649), we described some examples of how a PACE organization might comply with the requirement at § 460.98(c)(2). 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 the timeframe at § 460.98(c)(2). If the IDT determines that the participant should see an ophthalmologist, the PACE organization would be required to reach out to the ophthalmologist office to schedule the appointment within the timeframe at § 460.98(c)(2). We would not expect the delivery of the service (in this example, the actual appointment) to occur within the proposed timeframe, only that the PACE organization scheduled the appointment within that timeframe. Following the ophthalmologist appointment, if the IDT determines 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. During an audit or review, we would expect the PACE organization to have documentation to support compliance with the requirements in § 460.98(c). For example, a note that the appointment was scheduled or documentation that eyeglasses were purchased.

We believe that these explanations sufficiently establish how PACE organizations would comply with the proposed requirements at § 460.98(c), and do not believe codifying documentation standards or ''reasonable efforts'' at § 460.98(c) would enhance the provision's effectiveness. As per the current requirement at § 460.98(b)(4) (which we proposed to redesignate to § 460.98(c)(4)), PACE organizations must already document, track, and monitor the provision of services across all care settings. Since arranging and scheduling services are components of service delivery, we expect PACE organizations to maintain documentation of efforts to arrange and schedule services.

After consideration of the comments we received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c) to establish timeframes for arranging and providing services without modification.

Comment: With respect to our proposal at § 460.98(c)(1) and regarding the required timeframes for arranging and scheduling the dispensing of medications, many commenters agreed that PACE organizations must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires and supported CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications. However, most commenters disagreed with CMS establishing one timeframe for all medications, and instead recommended establishing separate timeframes for arranging and scheduling

the dispensing of emergency medications and non-emergency medications. These commenters advocated for allowing a longer maximum timeframe for arranging and scheduling the dispensing of non-emergency medications, and a shorter timeframe for emergency medications. Most of these commenters supported allowing up to 24 hours to schedule and arrange the dispensing of emergency or urgently needed medications and recommended that PACE organizations be allowed up to 2 business days to schedule and arrange the dispensing of non-emergency medications. Many commenters expressed that a longer timeframe for arranging and scheduling the dispensing of non-emergency medications would allow better prioritization of arranging and scheduling the dispensing of emergency medications. A commenter proposed a 48-hour timeframe for the coordination of all medications without explaining the basis for their recommendation. Another commenter did not support CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). As a result, PACE organizations must meet participant needs on evenings, weekends, and holidays as expeditiously as the participant's condition requires. Therefore, we are not persuaded to lengthen the proposed timeframe to arrange and schedule the dispensing of medications on the basis of standard business hours. Furthermore, we emphasize that the timeframe requirement at § 460.98(c)(1) does not pertain to the provision of medications, only to scheduling and arranging the dispensing of medications, which can typically be facilitated electronically. As explained in the December 2022 proposed rule (87 FR 79649), for the purposes of § 460.98(c)(1), 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. However, PACE organizations must still provide services, including medications, as expeditiously as the participant's condition requires, as per the newly redesignated § 460.98(c)(4).

Additionally, we are not persuaded to implement two distinct maximum timeframes for arranging and scheduling the dispensing of emergency and non-emergency medications. We understand that PACE organizations prioritize the delivery of emergency and non-emergency provider medication orders differently, because participants must receive services as expeditiously as their condition requires, taking into account their medical, physical, social and emotional condition in accordance with § 460.98(c)(4). However, we disagree with creating a distinction in regulation for arranging and scheduling the dispensing of emergency versus non-emergency medications, because we believe doing so would be difficult and impractical. For example, a medication that may be emergent to one participant may not be emergent to another, depending on factors that may not be apparent without information specific to the individual participant's medical, physical, social, and emotional condition. We think it is a fair and reasonable expectation that all medications be arranged and scheduled with the pharmacy within 24 hours. As previously explained, the timeframe requirement at § 460.98(c)(1) pertains to arranging and scheduling the dispensing of medications, which is related to, but distinct from, the service delivery requirement at § 460.98(c)(4). Therefore, although PACE organizations must arrange and schedule the dispensing of a medication no later than 24 hours after a primary care provider orders the medication, PACE organizations may deliver or provide the medication to the participant at a later time, as long as the medication is provided to the participant as expeditiously as their condition requires. We also believe this requirement is more easily accomplished than commenters seem to think. The timeframe to arrange or schedule a medication begins when an IDT member first approves or orders the service. Therefore, when a primary care provider orders a medication, they can submit the order to the pharmacy at the same time and satisfy this requirement. Based on many of the electronic medical records we have seen during oversight efforts, we think many systems are set up to ensure this happens seamlessly.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 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 a primary care provider orders the medication, without modification.

Comment: A few commenters expressed concern and made recommendations in regard to establishing maximum timeframes for the provision of medications. A commenter opposed the proposal at § 460.98(c)(1) and expressed that providing all medications within 24 hours was likely to cause harm to participants. The commenter gave the example that some medications, especially medications meant to treat chronic conditions in the elderly, should be explained and delivered thoughtfully in order to avoid misuse. Other commenters expressed concern that factors outside of the PACE organization's control, for example, pharmacy benefit manager (PBM) issues and national medication shortages, may delay access to medications and impact the PACE organization's ability to provide medications within the proposed 24-hour timeframe for arranging and scheduling the dispensing of medications. Additionally, a commenter recommended a maximum timeframe of 48 hours for the delivery of all medications.

Response: We believe these commenters may have misunderstood that the proposed maximum timeframe at § 460.98(c)(1) would apply to scheduling and arranging the dispensing of medications, not the provision of the medications. As discussed in the preceding comment response, our intention with this proposal was not to impose a specific timeframe for the delivery of medication, but to establish a maximum timeframe for the PACE organization to arrange and schedule the dispensing of medications. Considering the wide range of medications provided in PACE and varying needs of participants, we do not believe a specific timeframe for the provision of services, including medications, is feasible at this time. We agree with commenters that the delivery of medication would be based on the needs of the participant. We expect PACE organizations to provide medications as expeditiously as the participant's condition requires, as per the redesignated § 460.98(c)(4). Additionally, if PBM issues like medication shortages could impact participant care, the PACE organization must have contingencies in place to ensure participants have timely access to all necessary medications.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to

comments, we are finalizing our proposal at § 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 a primary care provider orders the medication, without modification.

Comment: While most commenters agreed with the premise of a maximum timeframe to arrange and schedule services other than medications, most of these commenters disagreed with our proposal that 7 calendar days was the appropriate timeframe to apply. Most commenters recommended we allow a maximum timeframe of up to 10 calendar days for arranging or scheduling these services.

These commenters made their maximum timeframe recommendation for services at § 460.98(c)(2) in consideration of potential delays in communication with provider offices. While a commenter cited general delays in communication from provider offices as another potential consideration for extending the maximum timeframe at § 460.98(c)(2), another commenter suggested that more time may be needed to coordinate scheduling appointments with providers whose offices may be closed on weekends and holidays. A commenter preferred a 10-calendar day maximum timeframe, in part, due to the time needed to coordinate with both the provider and participant based on provider availability and in consideration of participant preference. Additionally, some commenters suggested that the participant might not need certain services arranged or scheduled within the proposed timeframe to meet their care needs. One commenter did not specify a particular alternative maximum timeframe to arrange or schedule the delivery of all IDT-approved services other than medications. Rather, the commenter expressed that establishing a 7-calendar day maximum timeframe for scheduling or arranging specialty items such as power mobility devices and stair lifts would be challenging for the PACE organization to meet.

A few commenters expressed concerns with arranging and scheduling services with external providers, particularly specialists. A commenter that expressed this concern, suggested that delays in scheduling or arranging specialty services may not be within the PACE organization's control, and that ensuring compliance with the proposed requirements would be administratively burdensome and would divert resources from participant services. Another commenter recommended an exception to the proposed maximum timeframe and suggested up to 30 days for the PACE organization to schedule appointments with specialist providers.

Lastly, a commenter expressed that PACE organizations are unique with each participant requiring a personalized array of services, and that a single timeframe for service delivery could not meet all their needs.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). When we published the December 2022 proposed rule (87 FR 79650), we solicited comment on different maximum timeframes for arranging or scheduling the delivery of IDT-approved services, other than medications, and we specifically asked commenters that supported a longer timeframe than the proposed 7-calendar day maximum timeframe to include a rationale for how their alternative timeframe would ensure participant health and safety. While most commenters requested a longer timeframe, most commenters cited operational challenges for PACE organizations as the reason for a longer timeframe and did not address participant health and safety. However, during our oversight and monitoring efforts, we have not seen that the time and effort required to schedule services is a significant contributor to scheduling delays. Rather, we have observed that scheduling delays are often the result of a process breakdown after the primary care provider orders the service, which delays any attempts to schedule the service. For example, we have observed in numerous audits where a specialist service is ordered and the first documented attempt to schedule the appointment with the provider does not occur for weeks or months. We have not seen that PACE organizations expend significant effort making multiple unsuccessful attempts to schedule provider appointments to ensure the participant receives the service timely.

Since PACE organizations are required to provide services through employees or contractors (see § 460.70(a)), they should have mechanisms in place to ensure that they are able to quickly schedule or arrange services. As explained in the December 2022 proposed rule (87 FR 79649) and reiterated in this rule, to comply with the proposal at § 460.98(c)(2), PACE organizations must take affirmative steps to make sure the IDT-approved service was set up, scheduled, or arranged within the proposed timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. This requirement does not pertain to the provision of services, only to scheduling and arranging the service. However, PACE organizations must continue to provide services as expeditiously as the participant's condition requires in accordance with the current requirement at § 460.98(b)(4), which we proposed to be redesignated as § 460.98(c)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(2) to require PACE organizations to arrange or schedule the delivery of IDT-approved services, other than medications, as identified in paragraph § 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 member of the IDT first approves the service without modification.

Comment: Many commenters fully supported the proposed exception at § 460.98(c)(3) for routine or preventative services being excluded from the requirement in paragraph (c)(2).

Response: We thank the commenters for their support of our proposed criteria to exempt a PACE organization from the requirements at § 460.98(c) when certain conditions are met as proposed at § 460.98(c)(3)(i) through (iii).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(3) to exclude routine or preventive services from the requirements in § 460.98(c)(2) when requirements in § 460.98(c)(3)(i) through (iii) are met without modification.

E. 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. We have codified requirements pertaining to the interdisciplinary team (IDT) at § 460.102.

As discussed in the December 2022 proposed rule, changes to § 460.102 are the result of years of assessing PACE organizations' compliance with care coordination requirements established by the Act and our conclusion that further specification of these care coordination requirements in regulation would benefit participants and improve PACE organizations' understanding of how to comply with these requirements. In the December 2022 proposed rule, we proposed strengthening § 460.102 to identify the IDT's specific care coordination responsibilities, introduced maximum timeframes for the IDT's review of all recommendations from hospitals, emergency departments, urgent care providers, other employees, and contractors, and reiterated the IDT's role in timely service delivery.

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.

In the December 2022 proposed rule we proposed several amendments to § 460.102(d)(1). First, we proposed to redesignate current paragraph (d)(1)(ii) as paragraph (d)(1)(iii), and to add a new paragraph (d)(1)(ii). We also proposed to add a new paragraph (d)(1)(iv). We proposed 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 addition of ''for each participant'' emphasizes that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant. Since the inception of PACE, CMS has considered the IDT responsibilities to apply to all participants at the individual level. 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.

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. For example, we have seen problems with medication orders being implemented inappropriately, wound care not being done in accordance with orders, and other necessary services not being provided to the participant.

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 discussed in the January 2021 final rule, PACE organizations are responsible for furnishing comprehensive services to PACE participants across all care settings, 24 hours a day, every day of the year (86 FR 6034, 86 FR 6036). 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 to 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 proposed adding 5 subparagraphs at

§ 460.102(d)(1)(ii)(A) through (E) that further specify IDT coordination responsibilities across all care settings. We proposed 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 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 proposed 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 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. In the December 2022 proposed rule (87 FR 79652), 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 regulatory provision broad.

We proposed 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 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 proposed 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 proposed 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. Also, it is essential 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 proposed 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 were proposed for this provision. Then, we proposed 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, within maximum timeframes, as proposed in at § 460.102(d)(1)(iv)(A) through (C). As discussed earlier, the IDT is responsible for authorizing, approving and ordering all care, including care recommended from contracted providers. Through monitoring and oversight activities, we had 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 proposed timeframes for the IDT to review and act 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 proposed 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).

Per § 460.98(b)(4) (which we proposed to redesignate as § 460.98(c)(4)), PACE organizations must continue to provide services as expeditiously as the

participant's condition requires, taking into account the participant's medical, physical, social, and emotional needs. 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 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 proposed to redesignate as § 460.102(d)(1)(iii) and § 460.210(b).

We proposed 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 and expressed that we believed the 24-hour timeframe was necessary and reasonable due to the following considerations. First, the 24-hour 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 proposed 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 invited 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 requested commenters' perspectives on timeframes of 12 hours, 24 hours, 48 hours, and 72 hours from the time of the participant's discharge. We requested that such comments address how the commenter's preferred/recommended timeframe would ensure participant health and safety.

We proposed 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. As discussed in the December 2022 proposed rule (87 FR 79653), 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 recommended care. We explained that 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 that we would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 calendar days after the recommendation is made.

Additionally, we proposed 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 invited 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 asked about commenters' perspectives on whether we should adopt a 3-calendar day timeframe, a 5-calendar day timeframe, a 7-calendar day timeframe, or a 10-calendar day timeframe. We requested that commenters address how the alternative timeframes would ensure participant health and safety.

In the December 2022 proposed rule (87 FR 79654), we emphasized that these recommendation review and necessity determination 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 the full maximum timeframe 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.

Finally, we proposed 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 in accordance with the timeframes at § 460.98(c).

As discussed in the December 2022 proposed rule, 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 reiterate our belief that, by modifying this

provision, 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).

We summarize the comments received on the proposal at § 460.102 and provide our responses to those comments in this section of this rule.

Response to Comments

Comment: Some commenters expressed concern with the implementation of IDT care coordination responsibilities across all care settings as proposed in § 460.102(d)(1)(ii), and particularly in reference to IDT care coordination when participants reside in acute and long-term care facilities. Although most of the commenters that provided recommendations pertaining to § 460.102(d)(1)(ii) acknowledged that PACE organizations are responsible for overseeing participants' care at these facilities, they considered IDT involvement in daily care coordination activities for participants residing in care facilities to be functionally impractical and potentially harmful to participants. A few commenters thought that having the IDT order all necessary care for participants residing in care facilities could delay the provision of necessary care. In order to prevent delays in necessary care, a couple commenters recommended that the PACE organization delegate ordering care to care facility providers operating within their scope of practice. Another commenter suggested that the IDT does not have purview to order services provided by care facilities and recommended that the IDT take a consultative approach to overseeing care of participants staying in care facilities.

Another commenter noted different challenges with IDT involvement in daily care coordination at care facilities. These commenters remarked on the difficulty of ensuring daily communication between the IDT and the care facilities when care facilities experience operational issues, like staffing shortages, that may diminish their ability to promptly communicate with the IDT. The commenter asked CMS to provide guidance on how PACE organizations could strengthen care coordination with external healthcare facilities and suggested care coordination with the IDT be added into the contractual agreement between the PACE organization and care facility. This commenter also requested that CMS provide guidance on the types of documentation that would be needed to demonstrate that the IDT is meeting the care coordination requirements proposed at § 460.102(d)(1)(ii).

Response: The PACE program design is based on the IDT being responsible for authorizing and approving all care that is needed for PACE participants. Contractors, including medical specialty providers and contracted facilities, must agree to furnish only those services authorized by the IDT per § 460.70(d)(5)(i). Therefore, the IDT is currently required to authorize all participant care, regardless of the participant's care setting. PACE organizations may need to establish different coordination procedures and/or contract terms to ensure adequate communication with inpatient care facilities that meets the needs of participants. This does not mean that the PACE organization, or the PCP, needs to directly order all services for the participant that resides in acute and long-term care settings. While we know that some PACE organizations ensure that their PCP has privileges at contracted facilities (and therefore can order services directly), this is not always an option. While the PCP may not directly order all care, it does not absolve the IDT from ensuring that only approved or authorized care is provided. For example, even if a skilled nursing facility (SNF) PCP orders the participant's care, the IDT must authorize or approve the participant's care at the SNF.

As for documentation that demonstrates IDT compliance with the care coordination requirements proposed at § 460.102(d)(1)(ii) when a participant resides in a care facility, CMS expects to see documentation of communications with the facility that demonstrate the IDT's active monitoring and management of the participant's condition. This may include documentation from the admission of the participant, which includes all approved or ordered services (including medication) and ongoing documentation addressing any changes to the participant's care.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(ii) to require coordination and implementation of 24-hour care delivery that meets participant needs across all care settings without modification.

Comment: A commenter requested that CMS clarify the specific actions the IDT should take to ''act on'' recommendations as proposed in § 460.102(d)(1)(iv), which states that the interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists.

Response: In the December 2022 proposed rule (87 FR 79653), after introducing at § 460.102(d)(1)(iv) the requirement that the IDT review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists, we explained the specific components of the requirement in § 460.102(d)(1)(iv)(A) through (C). In addition to the IDT reviewing all recommendations from emergency or urgent care providers, employees, and contractors, we proposed that the IDT would determine whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs and arrange and furnish necessary care in accordance with § 460.98(c). Therefore, for the purposes of § 460.102(d)(1)(iv), ''act on'' means, in addition to reviewing and assessing these recommendations, the IDT would decide whether it is appropriate to approve the service and ensure the provision of any approved services. If the IDT determines a recommended service is not necessary, they must document their rationale for not approving or providing the service in accordance with the redesignated § 460.102(d)(1)(iii) and § 460.210(b).

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: A few commenters had concerns regarding the proposed requirement at § 460.102(d)(1)(iv) that the IDT review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists, specifically with respect to the involvement of the full IDT in recommendation reviews. They believed that CMS was proposing to require that the full IDT be involved in reviewing and approving these recommendations, which they considered administratively burdensome without added benefit to participant outcomes, particularly in emergency situations.

Response: We disagree with the commenters' interpretation of this requirement. The proposed regulatory text supports flexibility in determining which IDT disciplines review, assess and act on recommendations. Although § 460.102(d)(1)(iv) proposed to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, § 460.102(d)(1)(iv) further specifies that, in the cases of § 460.102(d)(1)(iv)(A) and (B), ''The appropriate member(s) of the interdisciplinary team must review all recommendations.'' The proposed language at § 460.102(d)(1)(iv) is similar to the language in § 460.121(h)(1), which allows the IDT to determine the appropriate IDT member or members to conduct a reassessment in response to a service determination request. For the proposed § 460.102(d)(1)(iv)(C), the IDT or a member of the IDT may authorize and approve the recommended service, which then must be promptly arranged and furnished.

Additionally, as discussed in the December 2022 proposed rule (87 FR 79653), we reiterate that the IDT can determine the appropriate IDT disciplines for reviewing recommendations. We do not anticipate that the full IDT would need to be involved in all decisions relating to recommendations made by hospitals, emergency departments, or urgent care centers. More likely, 1 or 2 IDT members would be responsible for these recommendations, and we believe typically this would be the PCP. The PCP in PACE is typically the only individual that can order care given a state's scope of practice laws, and the PCP has the additional responsibility of ensuring they manage the participant's condition, including the use of specialists and inpatient care, as required per § 460.102(c)(2). The example we provided in the December 2022 proposed rule involved a post discharge recommendation for antibiotics. In this instance, the PCP may be the only IDT discipline needed in order to appropriately review, assess, and act on the medication request, since the PCP is responsible for ordering care and medications. We clarify that the IDT has flexibility to determine which IDT disciplines should review, assess, and act on employee and contractor recommendations as well, which may not involve the full IDT. However, we emphasize that PACE organizations are responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant, and that the IDT should review recommendations with a multidisciplinary approach, as appropriate.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that CMS modify the proposed § 460.102(d)(1)(iv)(A) to extend the maximum timeframe for the IDT review of all recommendations from hospitals, emergency departments, and urgent care providers from 24 to 72 hours from the time of the participant's discharge. A few commenters recommended other maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers: 2 business days, 3 calendar days from the time the IDT was notified of the discharge, and 96 hours after documentation is included in the participant's medical record. One commenter did not recommend a maximum timeframe for IDT review of these recommendations but believed the proposed maximum timeframe to be unreasonable and shared the experience that it may be several days or weeks before the PACE organization receives emergency department recommendations. Another commenter was against imposing any timeframe for IDT review of recommendations from hospitals, emergency departments, and urgent care providers. These commenters advocated for more time to process these recommendations primarily due to concerns that hospitals, emergency departments, and urgent care providers tend to be providers external to the PACE organization for which the PACE organization has no purview. Additionally, some commenters noted that participants may not notify the PACE organization when they receive emergency or urgent care services. Thus, commenters expressed concern that PACE organizations may not be made aware of a participant's discharge or receive the recommendation from the external provider promptly enough for review of the recommendation within 24 hours from the time of the participant's discharge. The commenter that recommended a 2-business day maximum timeframe for the IDT review of these recommendations also recommended we keep long holiday weekends in mind when setting timeframes for recommendation reviews and that codifying a business day instead of a calendar day approach to the IDT recommendation review timeframe would give the PCP an opportunity to consider the information in the recommendation and develop a plan of care.

Several commenters interpreted the proposed maximum timeframe at § 460.102(d)(1)(iv)(A) to require the full IDT to be on-call to review all recommendations from hospitals, emergency departments, and urgent care providers on weekends. They expressed that having the full IDT present to review recommendations on weekends would impose unreasonable cost increases on the PACE organization, reduce IDT availability for participant care, and impact staff retention. Another commenter expressed general concern for requiring the IDT to review these recommendations within the proposed timeframe when the participant's discharge occurs on weekends.

Response: We carefully considered commenters' recommendations on lengthening the maximum timeframe to act on recommendations from hospitals, emergency rooms and urgent care providers. When we solicited comment on potentially lengthening the proposed timeframe of 24 hours, we asked commenters to indicate in their response how a longer timeframe would ensure participant health and safety. While commenters overwhelmingly requested a longer timeframe than 24 hours, all commenters indicated operational challenges as the basis for their recommendation and did not discuss how these longer timeframes would ensure participant health and safety. While we think there needs to be some consideration to operational challenges, our primary focus is on the participant and their needs. We are not persuaded to lengthen the timeframe to 72 hours or greater without some consideration of how the participants' needs would be addressed. However, we understand that sometimes, despite the PACE organizations' best efforts, 24 hours to act on recommendations may not be enough time. Therefore, we have modified the timeframe in which the appropriate member(s) of the IDT must review and determine the necessity of all recommended services from hospitals, emergency departments, and urgent care providers from our proposed 24 hours to 48 hours from the time of the participant's discharge as a compromise to the majority of commenters' preference for a 72-hour timeframe. We consider 48 hours to be a maximum timeframe, and therefore have also added language to take into

account the participant's condition, such that the finalized timeframe requirement is ''as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.'' We believe the 48-hour timeframe would not negatively impact participant well-being, as we reiterate that the 48-hour timeframe is a maximum timeframe, and PACE organizations ultimately must both review the recommendation and provide any necessary 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 IDT to act sooner than the maximum 48-hour timeframe. Since 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, which includes weekends and holidays, we believe the 48-hour maximum timeframe provides an appropriate level of protection for participants and accountability for PACE organizations regarding the types of services typically recommended after a participant receives urgent or emergency care. Additionally, as discussed in our earlier response to commenters regarding the IDT involvement in recommendation reviews, the IDT has flexibility to determine which IDT disciplines should review, assess, and act on recommendations. We do not expect the full IDT's involvement in every recommendation review. The recommendation review may be conducted by 1 IDT member. However, we continue to emphasize the importance of a multidisciplinary approach to participant care.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at 460.102(d)(1)(iv)(A) to require that the appropriate member(s) of the interdisciplinary team 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 as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

Comment: A commenter requested clarification regarding how the IDT's recommendation review, as proposed at § 460.102(d)(1)(iv) should be documented, and more specifically asked whether the IDT review of recommendations could be conducted verbally, or whether the reviewing provider should document their review of the order.

Response: We interpret this commenter's question as asking about documentation expectations for recommendations the IDT receives and reviews orally. At a minimum, the IDT is responsible for documenting recommendations from employees and contractors into the medical record per § 460.210(b)(4). Once the recommendation is documented, the IDT may have oral conversations regarding the necessity of that recommendation. Not all of those discussions would need to be documented. However, we expect to see the result of that discussion documented to demonstrate that the IDT assessed and considered the recommendations. If a recommendation was approved, we expect to see some evidence or documentation that the service was approved/authorized or ordered. If the recommendation was not considered necessary (and therefore not approved), the IDT is responsible for documenting the rationale for that decision per redesignated §§ 460.102(d)(1)(iii) and 460.210(b)(5). Additionally, if the IDT approves or orders the recommended service, the PACE organization must document, track, and monitor the provision of the service as per the redesignated § 460.98(b)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that we modify § 460.102(d)(1)(iv)(B) to extend the maximum timeframe for the IDT to review and make determinations on all recommendations from other employees and contractors. We had initially proposed 5 calendar days from the date the recommendation was made as the maximum timeframe, and most commenters recommended a maximum timeframe of 10 calendar days. Commenters' primary justification for extending the timeframe centered on the concern that providers external to the PACE organization might not cooperate in providing all necessary information to the IDT in a timely manner, which they considered beyond the control of the PACE organization, and potentially a situation that may unfairly penalize PACE organizations. Many commenters mentioned that PACE organizations may experience delays in follow-ups from specialist providers, since provider offices are often closed on weekends and holidays. A commenter did not recommend a specific alternative maximum timeframe for IDT review of other employee and contractor recommendations but expressed that the proposed 5-calendar day maximum timeframe was unreasonable based on their experience that PACE organization may not receive specialist recommendations for up to 2 weeks after the date the provider made the recommendation. Another commenter recommended that CMS not impose any timeframe for IDT reviews of contractor recommendations. This commenter considered any review timeframe for contractor recommendations unreasonable and echoed other commenters' concerns that PACE organizations may be penalized for situations outside of their control, such as when contracted providers do not communicate or provide necessary documentation timely to the PACE organization. This commenter also suggested that IDT review of all contractor recommendations would increase IDT responsibilities to the point of negatively impacting the time they can devote to participant care. A commenter asked that we clarify what the starting point for the review timeframe would be and recommended that we base the timeframe on when the PACE organization receives the recommendation rather than the date the recommendation was made.

Response: After careful consideration of the comments, we have decided to modify the proposed § 460.102(d)(1)(iv)(B). Specifically, we have modified the maximum timeframe in which the appropriate member(s) of the IDT must review and make necessity determinations for all recommended services from other employees and contractors from the proposed 5 calendar days to 7 calendar days from the date the recommendation was made. As previously mentioned in the December 2022 proposed rule (87 FR 79653), most PACE organizations audited in 2021 received citations of non-compliance for failing to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Most PACE organizations audited in 2022 and 2023 also received citations in this area. During our oversight and monitoring efforts, we have not observed that PACE organizations are routinely making multiple good faith attempts to receive

documentation, including recommendations, from specialist providers. Instead, we have seen numerous situations where PACE organizations make no attempt to obtain recommendations from specialists, and therefore are not aware of their recommendations until months later. The delayed receipt of specialist recommendations jeopardizes participant wellbeing by delaying necessary follow-up care and services. In consideration of our oversight and monitoring observations and commenter concerns, we believe the 7-calendar day timeframe is an appropriate compromise between the 5-calendar day timeframe we originally proposed and the 10-calendar day timeframe that the majority of commenters on this proposal preferred. We believe the 7-calendar day maximum timeframe offers additional flexibility to the IDT in terms of coordination with external providers, while continuing to prioritize participant wellbeing.

We continue to emphasize that the 7-calendar day timeframe is a maximum timeframe, and that the IDT 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, which may require action sooner than 7 calendar days. Although we recognize there may be logistical challenges involved with external provider communications, 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, and we decline to implement a timeframe that may result in a lower standard of care on the basis of communication delays by the contracted providers, as we expect PACE organizations to initiate communication and follow-up with external providers to ensure participants receive any necessary follow-on care and services. We also understand that some specialists may not provide written consult notes immediately following an appointment, but nothing would prevent the IDT from calling the specialist and documenting recommendations prior to receiving the complete consultation documentation. Additionally, as discussed in the December 2022 proposed rule, we reiterate that the § 460.102(d)(1)(iv)(B) timeframe begins the date the recommendation was made (87 FR 79654), not the date that the PACE organization or IDT receives the recommendation. In order to ensure participants receive the care they need, in the timeframe they need it, it is important that the timeframe begins when the recommendation is made, and that the PACE organization puts processes into place to get information relating to the recommendations quickly from providers.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at § 460.102(d)(1)(iv)(B) to require the appropriate member(s) of the interdisciplinary team to 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 7 calendar days from the date the recommendation was made.

Comment: A commenter suggested that we may have made an error when proposing at § 460.102(d)(1)(iv)(C) that services must be promptly arranged and furnished under § 460.98(c). The commenter did not believe the use of ''arrange and furnish'' was consistent with other sections in the proposed amendments to § 460.98, which specify maximum timeframes for arranging and scheduling services, but also that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

Response: Although the proposed and now finalized § 460.98 addresses timeframes for arranging and scheduling services, the redesignated § 460.98(c)(4) also states that 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. As discussed in the December 2022 proposed rule, the IDT must arrange (or schedule) the IDT-approved service within the maximum timeframes established at § 460.98(c)(1) and (2) and furnish the service as required by § 460.98(c)(4). (87 FR 79654).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv)(C) to require that, 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) without modification.

F. 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).

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. 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.

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 which included: a consolidation of discipline-specific initial assessments into a single plan of care for each participant within 30 days of the date of enrollment; documentation in the plan of care of the reasoning behind any IDT determination that certain services are not necessary to the care of a participant; and documentation in the plan of care that the participant was assessed for all services, even where a determination was made that certain services were unnecessary at the time.

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 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. As we discussed in the proposed rule, we have seen through our oversight and monitoring process that robust initial care plans become more sparse over time due to the omission of care originally included in the plan of care which is instead handled through discipline-specific progress notes as the participant's enrollment continues (87 FR 79655). In the proposed rule, we acknowledged that documenting detailed information about participant care and services in discipline-specific progress notes is necessary and an accepted standard practice, but argued that practice should not be done in lieu of a comprehensive plan of care that addresses the participant's needs because it results in individual IDT members providing care in an isolated and individualized approach (*Id.*).

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 noncompliance 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, we discussed in the proposed rule how 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 implemented by the IDT (*Id.*). 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. In the proposed rule, we stated that the purpose of participant/caregiver involvement is to ensure that they approve of the care plan and that participant concerns are addressed (87 FR 79656). 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.

As we discussed in the proposed rule, we believe it is prudent to implement additional requirements related to the minimum requirements for a participant's plan of care (*Id.*). The proposed rule included a discussion of our attempt to adopt language and requirements that are consistent with the long-term care facility regulation at § 483.21(b) when possible because these regulations require nursing homes to develop comprehensive and person-centered care plans that meet residents' needs. Since individuals who enroll in PACE must be deemed nursing home eligible, they have similar needs as those who receive services from nursing facilities (*Id.*).

First, we proposed 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. As we discussed in the proposed rule, 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 (87 FR 79656). Additionally, the IDT is required to reevaluate the plan of care on a semiannual basis at the current § 460.106(d); however, we proposed 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 also proposed 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. 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)). This language should also apply to PACE care plans, since they serve the same nursing home eligible population.

Next, we proposed 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 semiannual timeframe has posed issues for PACE organizations. We therefore proposed 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 proposed 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. As we discussed in the proposed rule, the current requirement is that the IDT must conduct reassessments when a participant experiences a change in participant status and the IDT must also reevaluate the participant's plan of care (87 FR 79656). 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. In the proposed rule, we argued that 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 (*Id.*). We reviewed the long-term care requirements which state that a resident must receive a comprehensive assessment within 14 calendar days after the date the facility determines, or should have determined there was a significant change in status in the resident's condition and the facility must use the results of the assessments to develop, review, and revise the resident's plan of care (*Id.*) In the proposed rule, we argued this is an appropriate standard to apply in PACE as well due to the similarities between the populations (*Id.*). As discussed later in this section of this proposed rule, we also proposed 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 proposed 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. As we discussed in the proposed rule, 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 (87 FR 79657). We also proposed to define at § 460.106(b)(3)(i) what constitutes a change in status. As we discussed in the proposed rule, what constitutes a change in status has not been previously defined and we proposed to adopt in PACE the requirement applicable to nursing homes at § 483.20(b)(2)(ii), but with language tailored to be specific to PACE (*Id.*). Therefore, the proposed requirement 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.

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 proposed 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. In the proposed rule, we recognized 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 (87 FR 79657). We proposed that the timeframe for reevaluating the plan of care starts when the participant is discharged from the hospital. Despite this proposed exception, we reminded PACE organizations in the proposed rule 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) (*Id.*).

We solicited comment on whether 14 calendar days is an appropriate timeframe to use or if 21 or 30 days would be more appropriate.

We proposed at § 460.106(c) to make certain modifications related to the content of a plan of care. As we discussed in the proposed rule, the current 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 (87 FR 79657). We discussed in the proposed rule that 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 which has caused members of the IDT to be unaware of the treatments and recommendations the participant has received from other members of the IDT or outside contracted specialists (*Id.*). Additionally, we discussed how 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 (*Id.*). Therefore, in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), we proposed to add language to the section to create minimum requirements for what each plan of care must include. As we discussed in the proposed rule, we considered the regulations at § 483.21(b) which specify the requirements for a comprehensive plan of care (*Id.*). Additionally, § 483.21(b) references § 483.24 (Quality of Life), § 483.25 (Quality of Care), and § 483.40 (Behavior Health), so we considered those sections as well. Therefore, at § 460.106(c), we proposed 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 proposed 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. As we discussed in the proposed rule, 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 (*Id.*). However, we proposed 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 which is consistent with nursing home requirements. As explained in the proposed rule, 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 (87 FR 79657). We observed that the nursing home care plan requirements at § 483.21(b) reference the behavior health requirements at § 483.40. Therefore, we proposed that chronic behavioral and psychiatric disorders that require treatment or routine monitoring also be included in PACE plans of care.

We proposed to limit what diseases must be included in the plan of care to

those that are chronic and require treatment or routine monitoring. As we discussed in the proposed rule, 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 (87 FR 79658). We also solicited comment on whether acute conditions should be included in the minimum content that a care plan must address.

We proposed 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). As we discussed in the proposed rule, the age of the PACE population and the co-morbidities that may impact the population makes addressing a participant's vision an important part of the care plan (87 FR 79658). We similarly proposed 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 proposed at § 460.106(c)(1)(iii) that a participant's plan of care must address the participant's dentition. This is consistent with the requirement at § 483.20(b)(1)(xi). We proposed at § 460.106(c)(1)(iv) that a plan of care must address the participant's skin integrity. This is consistent with the requirements at §§ 483.20(b)(1)(xii) and 483.25(b). We proposed at § 460.106(c)(1)(v) that the participant's plan of care must address the participant's mobility. This is consistent with the requirement at § 483.25(c). We proposed 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 is consistent with the requirements at §§ 483.20(b)(1)(viii) and 483.24(b). We proposed at § 460.106(c)(1)(vii) that the plan of care must address the participant's pain management needs. This is consistent with the requirement at § 483.25(k).

As we discussed in the proposed rule, the next few proposed requirements deviate from the nursing home requirements and are tailored specifically to the PACE program (87 FR 79658). We proposed 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. The 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. As we discussed in the proposed rule, PACE participants live in a variety of settings and the exact manner in which the organization meets the requirement may be different for each participant (*Id.*). For this reason, we proposed to include in § 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 proposed 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. As we discussed in the proposed rule, the 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, and the IDT must assess the participant's environment and living situation for potential factors that may make it unsafe for the participant (87 FR 79658). 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 proposed at § 460.106(c)(1)(x) that the plan of care must address the participant's home care needs. As we discussed in the proposed rule, this proposal would also deviate from nursing home guidance because, while nursing homes provide 24-hour care to residents living at the facility, PACE provides similar care through home care services (87 FR 79653). Therefore, we believe a participant's home care needs must be addressed through the plan of care. We proposed to establish at § 460.106(c)(1)(xi) that the participant's center attendance must be included in the plan of care. As we discussed in the proposed rule, 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 (*Id.*). We proposed at § 460.106(c)(1)(xii) to require that a participant's transportation needs be incorporated into the plan of care. As we discussed in the proposed rule, 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 (*Id.*). In addition, we proposed 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. As we discussed in the proposed rule, for participants who are not English speaking, or have some other difficulty communicating, addressing and resolving these needs preemptively can mean the difference between quality of care and participants not receiving the care they need (*Id.*).

We solicited comment on all items identified in proposed § 460.106(c)(1) and whether they should be required content in a plan of care for PACE participants. We specifically requested comment on whether to include acute diseases and/or acute behavioral and psychiatric disorders in the plan of care as part of the minimum criteria. We also solicited 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 proposed 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. As we discussed in the proposed rule, the PACE organization must also identify any service that will be provided to meet the participant's medical, physical, social, or emotional needs (87 FR 79659). We proposed 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 discussed in the proposed rule, we define services at § 460.6 to include medications because 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 (*Id.*). However, we also understand that medications may change frequently, and are typically documented in the medical record in way that would allow the IDT to understand all current, pending and discontinued medications. While we did not propose to require that all medications be identified in the plan of care, we solicited comment on whether the plan of care should include a comprehensive list of active medications.

We proposed 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 proposed 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 proposed rule noted that the IDT is already required to identify how each intervention will be implemented in § 460.106(b)(4); we proposed 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 (*Id.*). 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.

We proposed at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention. As we discussed in the proposed rule, 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)) (87 FR 79659). We explained in the proposed rule that our proposal at § 460.106(c)(5) is consistent with the intention of the current requirement; however, we believe that it is important when identifying a service to also identify the measurable goal for that service (*Id.*).

We proposed 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. As we discussed in the proposed rule, 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 (87 FR 79659). We explained in the proposed rule that our proposal is similar in intent, but would reduce ambiguity by specifying that the evaluation by the IDT should focus on determining whether the goal was met before deciding if the intervention needs to be continued, discontinued or modified (*Id.*). We further explained that if the participant met the goal, the IDT may decide to discontinue the service; however if the participant didn't meet the goal, the IDT may decide to modify or continue the intervention, and at that time, the IDT will need to determine both a new measurable goal and how that goal will be evaluated (*Id.*).

Finally, we proposed at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care. As we discussed in the proposed rule, 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 (87 FR 79659).

We proposed to move the requirements in § 460.106(c) to § 460.106(d) and make modifications to the existing requirements. We proposed to move the language in § 460.106(c)(1) to § 460.106(d)(1) and 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. As we discussed in the proposed rule, 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 (87 FR 79660). In the proposed rule, we reemphasized 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 (*Id.*). We proposed to include the language ''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.

We proposed 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. As we discussed in the proposed rule, the 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) (87 FR 79660).

We proposed to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with § 460.98(c). As we discussed in section VI.G. of the proposed rule, we have proposed additional criteria concerning the arranging and provision of services that are determined necessary by the IDT (87 FR 79648). We explained in the proposed rule that 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 (87 FR 79660).

As we discussed in the December 2022 proposed rule, although § 460.106(e) currently requires that the team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, 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 (87 FR 79660). We further discussed how 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.'' (*Id.*) Therefore, we proposed to split the existing language into two new paragraphs § 460.106(e)(1) and (e)(2). We proposed 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 proposed 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 proposed 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.

As we discussed in the December 2022 proposed rule, we have seen organizations have insufficient documentation related to participant plans of care despite the current requirement that the team document the plan of care, and any changes made to it, in the participant's medical record (87 FR 79660). We further explained how 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 no 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 (*Id.*). Therefore, we proposed 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. As we discussed in the proposed rule, our proposal is consistent with the current requirement, but ensures that the PACE organization understands that it must document all care planning requirements (*Id.*). 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 proposed certain modifications to § 460.104 to align with our proposed amendments to § 460.106. We proposed to remove most of the language currently in § 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. As we discussed in the proposed rule, we believe this will eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans (87 FR 79661).

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.

We solicited comment on these proposals. A summary of the comments received and our responses follow.

Comment: Most commenters appreciated CMS's clarification of semi-annual by modifying the requirement to 180 days. Several commenters expressed concern over the change in requirement from a semi-annual re-evaluation of the plan of care to a re-evaluation at least every 180 days. Those commenters stated the requirement is overly burdensome because it will require PACE organizations to monitor and track the care plan precisely and notify the IDT when the next care plan is due. A commenter requested clarification of whether the 180-day timeline restarts every time the plan of care is reevaluated or if it is predicated on the participant's enrollment date. A commenter requested that the requirement be modified from 180 days to the last day of the 6th month following the last reevaluation of the plan of care because it would provide PACE organizations an entire month to focus on care planning rather than having to calculate the 180 days exactly. Another commenter pointed out that 180 days is just short of six months, and that CMS should change the requirement to 185 days to allow for a full six months between reevaluations for plans of care.

Response: We thank commenters for sharing their concerns regarding the 180-day timeline being overly burdensome. We believe that providing a clear standard will reduce the ambiguity of the semi-annual care plan requirement currently in regulation. We are not persuaded by the argument that tracking the care plan by 180 days is overly burdensome as PACE organizations are already required to track care plans semi-annually. We have also consistently heard from both PACE organizations and advocacy groups that PACE requirements are overly vague and clarification of CMS's intent is appreciated whenever possible. For these reasons, we are not persuaded to extend the timeframe beyond the proposed 180-days or leave the requirement as it currently is written. Additionally, we clarify that we intend the 180-day timeline to restart every time a new care plan is finalized. We believe this is consistent with other parts of the regulation that contemplate care plans being developed within specific timeframes (for example, §§ 460.104(b) and 460.106(a)) and also the service determination request language which discusses requests made ''prior to completing the development'' of the initial plan of care (see § 460.121(b)(2)). For example, if a participant experiences a change in health status, the participant must be assessed, and a new care plan must be developed and implemented. The participant's next care plan would then be due 180 days from the date the latest care plan was finalized. To ensure there is no ambiguity on when the timeframe begins, we are finalizing the proposed requirement with a modification to the regulation text to state that the 180-day timeline starts from the date when the last care plan was finalized at § 460.106(b)(2).

Comment: Multiple commenters requested that CMS extend the timeframe to conduct unscheduled assessments following a change of status from the 14-day timeline that was proposed to a 30-day timeline to allow PACE organizations more flexibility in complex cases and more time to coordinate with providers outside of the PACE organization's network. A commenter questioned CMS's decision to hold PACE organizations to the same standard as long-term care facilities when it is not clear whether the 14-day timeline used by these facilities improves care. A few commenters requested that CMS add a participant being discharged from a SNF as an exception to the 14-day timeframe, similar to the exception proposed for participants who are hospitalized. These commenters argued that it is beneficial for the participant to be as stable as possible before conducting assessments and developing a care plan. These commenters suggested that if a participant is placed in a SNF for a short-term stay, or another similar environment, the IDT should delay the reassessment timeframe until discharge, similar to the hospital exception. A commenter requested CMS consider providing an exception process to the timeline to allow PACE organizations an exemption when needed, but to limit abuse by requiring 85 percent of care plans to meet the regulatory timeframes to be considered compliant. Another commenter requested that CMS clarify when the timeline would begin for care planning purposes if a PACE organization failed to determine, but should have determined, that there had been a change in the participant's health or psychosocial status.

Response: We thank the commenters for their suggestions to extend the timeline to conduct an unscheduled re-evaluation of the care plan following a change in status. We understand the concerns expressed by commenters about the ability of PACE organizations to obtain necessary information from outside sources, such as hospitals, to complete assessments of the participants after a change in status. We had solicited comment on whether the timeline should be 14, 21, or 30 days and, if commenters believed a different timeline was more appropriate for PACE, why PACE should be held to a

different standard than long term care facilities. While most commenters requested 30 days, we were not persuaded by the commenters' arguments for why this longer timeframe was justified. PACE organizations must have processes in place to ensure their contracted providers are promptly communicating information relating to the participant's condition. Incidents that prompt a change in status reassessment are not minor events, but situations that have a direct impact to a participant's ability to function, and therefore, they need to be considered and addressed as expeditiously as the participant's health requires. As we have stated previously, because PACE and long-term care facilities serve the same vulnerable population, we feel aligning the requirements ensures participants receive the same quality of care they would receive in a nursing home or other SNF. We are also not persuaded to add an exception to the timeframe for conducting a re-evaluation of the care plan to include a participant's discharge from a SNF. SNFs are contracted with the PACE organization, and the PACE organization should already have processes in place to conduct assessments of participants when they are at those facilities as needed. Additionally, while commenters requested exceptions for ''short term'' stays in a SNF, ''short term'' is an undefined period of time which will change for every participant in every situation. While some participants may experience a short term stay of a week, other participants may be admitted for a ''short term'' stay and end up residing in the SNF for a month or even longer. Delaying those participants' re-evaluations until after discharge would be inappropriate as the participant may end up residing for long periods in another care setting without a care plan that is appropriately tailored to their needs. We would note, nothing in our modification prohibits a PACE organization from conducting change in condition assessments and care plans on a more frequent basis. If the PACE organization determines that the participant should be re-assessed following the discharge from the SNF, it is encouraged to do so.

As for the language that the timeframe begins 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; this language is meant to convey that the trigger for the timeframe is when the change in status event occurs, even if that event happens prior to the PACE organization becoming aware of it. For example, if the participant has a stroke with hemiplegia on a Monday, and the PACE organization becomes aware of the stroke 2 days later, the 14-calendar day timeframe begins the date of the stroke, not the date the PACE organization becomes aware of the stroke. However, if the participant is hospitalized because of the stroke, the 14-calendar day timeframe would begin upon discharge from the hospital. We are finalizing the 14-calendar day timeframe as proposed.

Comment: Several commenters requested that CMS modify the proposal on the required content of plans of care to focus on what is most important and relevant to participants' needs as identified by the IDT in collaboration with the participant and/or designated representative. A few commenters also requested that CMS clarify that the proposed changes to the content of the care plan will not interfere with the participant's views and wishes, including the participant's desire to decline certain plan goals. A few commenters expressed concern that the minimum requirements for the content of care plans would include such a high level of detail that it would impact the IDT's time and resources and create administrative burden. A commenter stated that long-term care facilities and PACE organizations are different and should not be held to the same standards, and asked for clarification of how CMS would determine the validity of an assessment for a participant who has no needs in a specified area. A commenter requested that CMS clarify what the word ''need'' means in the context of the care plan, and whether that refers to an assessed medical need or a need the participant believes they have. Another commenter stated that it was impractical and duplicative for IDT members to incorporate their individual notes and diagnoses from the medical record into a care plan for all participants.

Response: We thank commenters for sharing their concerns on the proposed required content to the plan of care. Our intent in proposing required content for the plan of care wasn't to override participant's wishes and desires for what is included in their individual plans of care, but instead to ensure that all participants are equally assessed for services that meet their needs, and to ensure the care plan is a comprehensive document that reflects an accurate picture of the care a participant receives. In the event a participant is assessed for a service that they do not wish to include in their plan of care, we would expect the PACE organization to document that the participant was assessed for the service and requested it not to be included in their plan of care. Additionally, if the IDT determined the participant did not have any identified needs in a particular area, they would indicate that in the plan of care. For example, if the participant is assessed as having perfect vision, the care plan content for vision may include an optometry appointment once a year without any further goals or interventions. Or the IDT may note that there are no current needs in a particular area, such as skin integrity. When determining a participant's needs in a particular area the IDT should use all available information including recent assessments to ensure the care plan accurately reflects the participant's condition in a particular area. Per our changes to § 460.121(b)(2), as discussed in section IX.L of this final rule, when a participant believes they have a need, we would expect the IDT to assess the participant for that need to determine if the need is present. Then the IDT would assess what services or interventions are necessary to meet that need, just as the IDT determines whether any request for a specific service is necessary to improve and/or maintain a participant's medical, physical, emotional, or social wellbeing. Then we would expect the IDT to document the request for assistance with the stated need, the IDT's determination, and in the event the need was determined not to be present, the IDT's reasoning for that determination. We would review the available documentation in the medical record to determine if the participant's needs were appropriately assessed and addressed.

We understand that long-term care facilities and PACE organizations are not the same, but they share some important similarities. They are both direct care providers serving nursing home eligible participants. Therefore, we do not believe it is inappropriate to adopt long-term care standards in order to ensure equitable access to care among the vulnerable populations served.

We are not persuaded that requiring the IDT to record its diagnoses into the care plan as well as the medical record is duplicative. PACE was created to care for the individual as a whole, with the IDT and care planning being important components of the program's success. If the care plan does not include all current diagnoses from the different IDT disciplines, then the participant may not receive all the care for which they have been approved. As we stated in the proposed rule, we have seen as part of our oversight and monitoring activities that PACE organizations rely heavily on

discipline specific progress notes causing participant care plans to be sparse and not fully detailing the care received by the participant (87 FR 79655). If the IDT is not fully aware of all of a participant's comorbidities as well as any developments in the participant's medical, physical, emotional, and social status, the participant's planned treatment and services may not be adequate to meet the participant's needs. We are finalizing the required content of the care plan as proposed.

Comment: Multiple commenters agreed with CMS's decision not to include acute diseases or medications in the care plan requirements. A commenter supported CMS's inclusion of vision in the content requirements of the care plan and requested that CMS require PACE organizations to report the number of participants referred to a doctor of optometry for a comprehensive eye exam.

Response: We thank the commenters for their support of the proposed required content of the plan of care. We agree with commenters that the inclusion of acute diseases is not always appropriate in the plan of care and are finalizing the proposed required content without inclusion of acute diseases or medications; however, as we stated in the proposed rule, nothing prevents a PACE organization from including acute diseases or medications in the care plan if they so choose (87 FR 79659). Additionally, while we appreciate the support for including vision as required care plan content, the collection of data including optometry appointments is outside the scope of this rule.

Comment: A few commenters requested CMS refer to the National Consensus Project for Quality Palliative Care to include interventions such as palliative care, non-pain symptoms, caregiver burden, participant's cognitive status and decision-making ability, financial vulnerability, and spiritual concerns.

Response: While we agree with the commenters that interventions for other areas in a participant's life are an important consideration for treating a participant's medical, physical, emotional, and social needs, we are not persuaded to require additional content regarding non-pain symptoms, caregiver burden, participant's cognitive status and decision-making, financial vulnerability, or spiritual concerns. While we agree that these specific areas may be relevant to some participants, we believe it is such a personal matter that we are not adding them to the minimum criteria. However, we encourage PACE organizations to consider whether other interventions would be appropriate when developing the care plan based on the participant's needs and other regulatory requirements, including requirements related to participant rights. We may consider proposing additional minimum content for the plan of care in the future. We would note that nothing in our proposal would prevent PACE organizations from including additional content in the care plan if they so desired. We also extensively discussed the proposed palliative care requirements in section IX.G, Specific Rights to Which a Participant is Entitled, where we proposed to require PACE organizations to define comfort care, palliative care, and end-of-life care, and obtain consent from participants and/or their designated representatives prior to implementing comfort, palliative or end-of-life care. We believe our proposal in that section to require PACE organizations to explain the different treatment options, provide written information of those treatment options, and obtain written consent prior to initiating palliative, comfort or end-of-life care services is the appropriate avenue for addressing palliative care interventions. To the extent that a participant's services change as a result of their designation of palliative care, comfort care or end-of-life care, the IDT should consider how those changes impact the care plan and whether modifications to the care plan are necessary. Therefore, we are finalizing the required content of the plan of care as proposed.

Comment: Multiple commenters requested CMS to modify the proposed participant and/or caregiver participation requirement to allow PACE organizations to document attempts to engage the participant and/or their caregiver. These commenters stated that often participants and/or caregivers are averse to participating in the care planning process. Alternatively, a few commenters suggested CMS grant the IDT a grace period of 15 days to accommodate the participant's and/or caregiver's availability and willingness to review the care plan prior to finalization or to allow PACE organizations to finalize care plans prior to obtaining participant and/or caregiver approval. With respect to the latter alternative, a commenter stated that if the caregiver and/or participant do not approve of the care plan after it has been finalized by the PACE organization, the care plan can be reviewed and revised at that point. Another commenter requested CMS modify the proposed requirement to clarify how PACE organizations can prove compliance when participants and/or their caregivers do not participate in the care planning process.

Response: We thank commenters for sharing their concerns regarding the proposed requirement to include participants and/or caregivers in the plan of care development and implementation process. We recognize that some participants and/or caregivers may be averse to participating in the care planning process. However, we would point out that there are different methods the IDT may use to involve the participant. Some participants may want to participate in the IDT meeting where the care plan is discussed and developed. Other participants may want to participate less in the care planning process. In those cases, we would expect, at a minimum, documentation to demonstrate that the care plan was fully reviewed with the participant, and that any concerns were addressed, prior to the care plan being finalized. It is important that participants and/or caregivers are active in discussions regarding the participant's needs. A collaborative approach to care planning allows participants and/or caregivers to be actively engaged in the care participants receive. As we stated in the proposed rule, often we see through our oversight and monitoring process that participants and/or caregivers are only informed of the new care plan after it has been completed by the IDT (87 FR 79660). We also believe this requirement addresses commenters' concerns, discussed in an earlier comment summary, regarding ensuring the participant's views and wishes are taken into consideration during the development of the plan of care. The best way to ensure that the care plan satisfies the participant's goals for care is to include the participant in the care plan discussion. Therefore, we are finalizing the participant and/or caregiver participation requirements as proposed.

We are also not persuaded by the argument to extend the timeframe beyond 180 days to allow a grace period for finalizing the care plan to accommodate participants' and/or their caregivers' availability and willingness to review the care plan. However, nothing prevents a PACE organization from factoring in their own grace period when calculating the 180-day timeframe to ensure the PACE organization has enough time to meet with the participant before the deadline. For example, if the participant is historically difficult to reach, the IDT may decide to start the care planning discussions a few weeks prior to the

180-day deadline in order to allow ample time to finalize the plan of care.

Our intent in proposing the participant and/or caregiver participation requirement was to reduce the instances of participants and/or caregivers being presented with a finalized care plan after the IDT has completed its assessments and recommendations. As we stated in the proposed rule, 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'' (87 FR 79660). While we understand that participants and/or caregivers may not wish to participate in the care planning process, they should at least be given the opportunity prior to the care plan being finalized. We would expect a PACE organization to document attempts to engage the participant and/or caregiver in the care planning process and would consider those attempts in our review of a PACE organization's compliance with this requirement.

After considering the comments, we are finalizing the proposed changes to § 460.106 in part, with a modification to the language at § 460.106(b)(2) to clarify that the required timeline for the care plan reevaluation is 180 days from the date when the previous care plan was finalized.

G. 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 the proposed rule, CMS proposed 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 participants access to necessary covered items and services 24 hours per day, every day of the year. We 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), we 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, as we discussed in the proposed rule, 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 (87 FR 79661). We also stated in the proposed rule that we have seen organizations 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 (*Id.*). 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. We argued in the proposed rule that 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 (*Id.*). We further stated that it is essential that PACE participants understand their right to receive all treatments in the PACE benefit package that are necessary and appropriate, and that they clearly understand their rights as their health transitions throughout their time in the PACE program (*Id.*).

For the foregoing reasons, we proposed certain modifications to § 460.112. First, we proposed 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. As we discussed in the proposed rule, we considered the language in § 460.92 related to services meant to improve or maintain the participant's health condition as well as nursing home regulations at § 483.21(b)(1)(i), which require care plans to describe ''the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being'' (87 FR79661).

In addition, we proposed 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. As we discussed in the proposed rule, although the right to access emergency care services currently appears at § 460.112(d), we believe that it relates to the right to treatment, and therefore, we proposed to move the text of current § 460.112(d) to new § 460.112(a)(2) (87 FR 79662).

In the 1999 PACE interim final rule, we codified at § 460.112(a) (which we proposed 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). We also codified at § 460.112(e) the right of participants to participate fully in all treatment decisions. As we discussed in the proposed rule, § 460.112(e)(1) 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 (87 FR 79662). We stated in the proposed

rule that 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'') (*Id.*). Therefore, we proposed 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. As we stated in the proposed rule, 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 (*Id.*).

In the 1999 PACE interim final rule (64 FR 66254), we codified the participant's rights to receive accurate and easily understood information at current § 460.112(b) (which we proposed to redesignate as § 460.112(c)). In the 2006 PACE final rule, we further stated that this information was necessary for participants to ''comprehensively assess differences in their health care options'' (71 FR 71295). We 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). We argued in the proposed rule that a participant's designated representative should receive the same accurate, easily understood information the participant receives in order to make informed decisions on behalf of the participant (87 FR 79662). We proposed 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.

The proposed rule at 87 FR 79662 discussed how we have seen as part of our audit and oversight activities that PACE organizations used the terms palliative care, comfort care, and end-of-life care, without providing participants with clear information on how the PACE organization is defining those terms or offering clear explanations of whether participants who opt to receive those forms of treatment will also continue to receive curative treatments. Although we did not propose 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. Therefore, we proposed 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 proposed that the written notification to participants must explain four different aspects of the treatment options, which we outlined in proposed § 460.112(c)(5)(i) through (iv).

First, we proposed 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. As we discussed in the proposed rule, a participant should have the right to fully understand the care they are agreeing to receive prior to that care being initiated (87 FR 79662).

As 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. As we discussed in the proposed rule, we have seen through audit that some PACE participants receive palliative care and/or comfort care in addition to curative treatment; however, we have also seen participants receive palliative care and/or comfort care instead of treatment meant to improve or maintain the participant's health condition when the participant was unaware that in choosing palliative care, they were also choosing to forego curative treatments (*Id.*). We stated that providing palliative care only services may be appropriate in some instances, but we believe it is important that participants fully understand what they are agreeing to when they enter into palliative or comfort care status (*Id.*).

As 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. As discussed in the proposed rule, 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 (87 FR 79663). We further explained that PACE organizations that provide palliative care services in conjunction with curative treatment may not have to provide a detailed analysis and could instead include language in their explanation that palliative or comfort care will not impact existing services (*Id.*).

As 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 proposed 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). That includes the right to participate 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. As we discussed in the proposed rule, we have seen situations where participants or their designated representatives want to stop palliative care or comfort care when they realize this means they will no longer receive other services, and they do not know they have the right to revisit prior treatment decisions (87 FR 79663). As we discussed in the proposed rule, participants should be clearly informed, in writing, that they have the ability to change their mind on these important treatment decisions (*Id.*).

In the 1999 PACE interim final rule (64 FR 66255), we 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 the proposed rule, we proposed to amend § 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 proposed 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 proposed at § 460.112(e)(1)(i) to establish that a participant's right to make health care decisions includes the right to have all treatment options fully explained to them. As we discussed in

the proposed rule, a participant cannot make an informed health care decision without fully understanding the options available (87 FR 79663).

As 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 proposed 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 proposed 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.'' As we discussed in the proposed rule, 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 (87 FR 79663).

We proposed 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.

At § 460.112(e)(2)(i), we proposed 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. We proposed 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). As we discussed in the proposed rule for § 460.112(c)(5), 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 (87 FR 79662). We proposed 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 explaining the treatment options in a way that is understandable to the participant so that the participant has a full understanding of their options. Finally, we proposed 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. As we discussed in the proposed rule, we have seen that some organizations stop treatments to improve or maintain a participant's condition when a participant enters palliative care or comfort care, and therefore, we believe it is especially important that participants or their designated representatives are in agreement with these treatment options, and consent to receiving this care (87 FR 79664). We proposed 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. As we emphasized in the proposed rule, 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 (*Id.*). That directive is distinct from the notification proposed at new § 460.112(e)(2), which would 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), we 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), we 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 as 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 (*Id.*). 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. As we discussed in the proposed rule, we believe that § 460.112(g) should also reference the right to request a service determination request, which is the first step in the appeals process. Therefore, we proposed 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 proposed 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 this burden in the collection of information section of this final rule.

We solicited comments on these proposals and a summary of the comments received and our responses follow.

Comment: A majority of commenters requested that CMS proactively define the terms palliative care and end-of-life care in the final rule, rather than leaving the definition up to each PACE organization. Several commenters referenced CMS's current definition of palliative care in the hospice regulations at § 418.3. A commenter requested that palliative care be defined as care that focuses on improving the quality of life and easing suffering. Most commenters requested CMS to stop using the term ''comfort care'' as they stated that it is not a medically defined term and is more a term of art. Additionally, a majority of commenters requested that CMS stop using the terms interchangeably to avoid furthering the misconceptions around the different terms. A few commenters requested that CMS clarify that end-of-life care is a comprehensive set of services to provide for the physical, psychosocial, spiritual, and emotional needs of terminally ill patients and their family members.

Response: We thank commenters for their feedback. Commenters are correct that the hospice regulations define palliative care at § 418.3 as ''patient and family-centered care that optimizes the quality of life by anticipating, preventing, and treating suffering.'' We

agree that the palliative care definition in the hospice regulations is a national standard and we encourage PACE organizations to consider this definition for use in their own program. We do not intend to define these terms for purposes of the PACE regulations as a part of this rule; however, we will consider defining these terms in future rulemaking. Our intent with this proposal is to ensure that PACE participants have notice of how the terms are defined by the PACE organization and how the definition impacts the care they receive. As we stated in the proposed rule, we have seen through our oversight and monitoring process that PACE organizations are using these terms interchangeably without providing participants with clear definitions or an explanation of how the different terms impact the treatment options available to participants (87 FR 79661). While we do not want to add to the misconceptions around the terms, we routinely see these three terms in PACE organization medical records, without clear definitions applied to them. This provision is intended to provide clarity for participants when PACE organizations use any of these terms in their explanation of benefits. Therefore, we will be finalizing the requirement that PACE organizations provide participants with clear, written definitions to increase transparency and understanding of what services participants can expect to receive in lieu of or in addition to the services they were receiving prior to opting for palliative, comfort, or end-of-life care without modification.

Comment: Several commenters objected to the proposed requirement that the PACE organization obtain written consent from the participant and/or their caregiver prior to implementing palliative care on the grounds that it would be administratively burdensome and unnecessary, as it was their understanding that palliative care is intended to be provided concurrently with curative care. A commenter requested that the proposed regulation language be altered to require consent only when the PACE organization implements a plan of care no longer considered curative or life-prolonging, and instead is focused on only palliative care or end-of-life care.

Response: We thank the commenters for sharing their concerns regarding the proposed requirement for written consent prior to implementation of palliative care. While we understand that palliative care may be provided in addition to all other services at some organizations, that is not always the case. As we stated in the proposed rule, we have seen as part of our oversight and monitoring efforts that some PACE organizations are not continuing to provide curative treatment once a participant has elected to receive palliative care (87 FR 79661). In these situations, some participants are not aware that by consenting to receive palliative care, they are consenting to stop curative treatment in favor of palliative only care. In some cases, the participant may believe they are consenting to receive palliative care in conjunction with continuing to receive curative treatment. We disagree that requiring consent from participants prior to implementing palliative care would be overly burdensome. If a PACE organization offers palliative care in addition to or in conjunction with curative treatment, then the notice required in this provision is minimal. The PACE organization would need to provide a description of the term or benefit and would need to indicate that this is done in addition to all other services received by the participant. This notification could be provided to the participant early on in their enrollment through either enrollment materials or the care plan. However, if palliative or end-of-life care is offered in lieu of curative treatment, participants need to be informed that choosing palliative or end-of-life care will result in a cessation of curative treatment and participants need to consent to the change in treatment. It is only when a participant's services will change as a result of moving to palliative care, comfort care, or end-of-life care that the notification must become more tailored and include a detailed description of how the services being received by a participant will be impacted. We are finalizing the consent requirement as proposed because we believe it will protect participants from agreeing to forego curative treatment when that is not their intent.

Comment: A few commenters expressed support for our proposal to require PACE organizations to fully inform participants about applicable treatment options, including any policies that would limit participants' ability to receive curative treatment. These commenters also supported our proposed requirement that PACE organizations obtain consent from participants before making changes to the treatment plan, as well as our proposal that participants have the right to revoke consent at any time. A commenter expressed concern that in some cases participants have decided to reinstate disease-directed care, but the care was not effectuated until the first of the month following the participant's request. The commenter requested that we clarify that if participants revoke or withdraw their consent to palliative care-only services, that decision to reinstate curative care should be effectuated immediately.

Response: We thank the commenters for their support for our proposal. We share the commenter's concerns about the need to effectuate a return to curative treatment immediately if the participant revokes their agreement for palliative only care. When a participant decides to return to curative treatment and/or forego palliative only care, the PACE organization must act on that information immediately. We would consider this a change in participant status, and per the changes to the plan of care that we are finalizing in section IX.F of this rule, the PACE organization would be required to reassess the participant and re-evaluate the participant's plan of care.

Comment: Several commenters expressed a desire that PACE organizations have the ability to continue to provide and/or coordinate hospice care through a Medicare Advantage or other hospice program to allow participants to remain enrolled in PACE. A couple of commenters requested that the proposed regulation language be altered to require PACE organizations to inform participants of their rights regarding hospice care both within and outside of the PACE program. Specifically, these commenters requested that PACE staff be required to explain to participants about the Medicare hospice benefit and the participants' right to enroll, including an explanation that participants must disenroll from PACE to enroll in the Medicare hospice benefit. A commenter also requested that CMS require PACE staff to disclose any contractual relationship the PACE organization has with hospices in the community. Finally, a few commenters requested that CMS should strengthen requirements regarding the IDT's capabilities to ensure they have sufficient expertise in pain and symptom management for participants with serious illness or who require end-of-life care.

Response: We thank commenters for their concerns. Although we have proposed to require PACE organizations to inform participants of all treatment options, including palliative and end-of-life care, and how those options may impact curative treatment, nothing we have proposed would remove the ability of PACE organizations to continue

providing hospice-like services or contracting with community hospice programs to provide hospice services to participants. The enrollment agreement that PACE participants enter into with the PACE organization is required to provide information regarding disenrollment, including the requirement to disenroll from PACE in order to receive and enroll in the Medicare hospice benefit per § 460.154(i). The PACE organization is also already required to disclose contractual relationships to participants upon enrollment and throughout the time the participant is enrolled in the PACE program. Therefore, we are not persuaded that an additional requirement is needed in regulation regarding hospice care.

As for ensuring that the IDT includes the expertise to provide meaningful end-of-life care to participants, in the April 12, 2023 final rule, we modified the proposed regulation for contracted services to include palliative medicine. Effective January 1, 2024, PACE organizations are required to staff and/or contract with palliative medicine specialists. At this time, we do not believe it is necessary to include a palliative care specialist on the IDT as a routine role. The disciplines that participate in the IDT are the minimum required, but the IDT may always include additional personnel or specialists as it sees fit. To the extent an IDT wants to bring in a palliative care specialist to assist with developing an end-of-life plan of care, it is allowed and encouraged to do so.

Comment: A commenter requested that the language in the regulation be altered to require written notification only when a participant is moving to palliative only care or end-of-life care as it will not be beneficial to the participant and may be overly burdensome to PACE organizations.

Response: As we have stated previously, through our oversight and monitoring efforts, we have seen instances of participants transitioned to palliative-only care or end-of-life care without the PACE organization explaining to the participant that this transition means the participant will no longer receive curative treatment. We believe that requiring written notification to the participant regarding the implementation of palliative, comfort, or end-of-life care will reduce confusion among participants of what care they expect to receive. As we stated in response to a previous comment, if a PACE organization provides palliative care in addition to curative treatment, then inclusion of that additional benefit in the enrollment materials provided to the participant at the time of enrollment or the inclusion of information regarding the palliative care benefit in the participant's care plan would likely be sufficient to meet this requirement.

Comment: A commenter supported the proposed requirement that participants have a right to request services via a service determination request in addition to their right to file a grievance or appeal.

Response: We thank the commenter for their support and are finalizing this provision as proposed.

After considering the comments, and for the reasons set forth in the proposed rule and in the previous responses, we are finalizing the changes to § 460.112 as proposed.

H. 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. 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. In the December 2022 proposed rule (87 FR 79452), we proposed 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 proposed certain adjustments that would align the requirements with the service determination process in § 460.121 for consistency.

First, we proposed to amend § 460.120(a) by removing the current paragraph header, which reads ''Process to resolve grievances.'' and added in its place a new paragraph header ''Written procedures.'' Specifically, we proposed 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. In addition, we proposed to further amend § 460.120(a) by removing the list of individuals who can file a grievance, as we proposed to create a new paragraph that outlines who may submit a grievance at § 460.120(d). We proposed 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. 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 the purposes of PACE. Specifically, in the December 2022 proposed rule, we discussed how the grievance definitions in other managed care programs and care settings, specifically in MA and in nursing homes, could inform and enhance the grievance definition for PACE.

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. 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 proposed to include in our definition of a grievance that a request for remedial action is not required.

We also proposed 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 solicited 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 solicited comment on whether we should consider adopting the following definition of grievance for purposes of the PACE regulations: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or its contractors' operations, activities, or behavior, regardless of whether remedial action is requested.

We proposed to redesignate current § 460.120(b) as § 460.120(c), change the title, and amend the regulation text. Specifically, we proposed to change the title from ''Notification to participants.'' to ''Grievance process notification to participants.'', to differentiate from notifications related to grievance resolutions, and to add the requirement that the grievance process notification be written in understandable language. We proposed 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 solicited 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 solicited 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 proposed 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. 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 proposed at § 460.120(c)(2) that the grievance process notification must inform participants 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. 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 proposed 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.

We proposed 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 submit 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 the amendments we proposed, would require PACE organizations to have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances. We proposed to amend the list of individuals who can submit a grievance to include the participant's caregiver. We believe the addition of the participant's caregiver 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.

As we explained in the January 2021 final (86 FR 6018), we have not historically considered ''caregivers'' to include employees or contractors of the PACE 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 submit a grievance under § 460.120. In the December 2022 proposed rule (87 FR 79667), we solicited comment on our proposal to amend the list of individuals who can submit a grievance to include a participant's caregiver.

We proposed to add these rules around the submission of grievances in new paragraph § 460.120(e). We 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. We 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 proposed 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 two different issues, and both may need to be investigated in order to appropriately resolve the grievance. The PACE organization may determine through its investigation 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 proposed 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. In our proposal for the PACE grievance regulation, we proposed 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 proposed 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 proposed § 460.120(h) would establish requirements for the processing of expedited grievances. Specifically, we proposed 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. We proposed 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 proposed 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 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 proposed to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions

must include a minimum of three requirements. First, we proposed at § 460.120(i)(2)(i) that the notification must include a summary statement of the participant's grievance including all distinct issues. Second, we proposed 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. Third, we proposed 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) proposed requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, we proposed 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 proposed to establish 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 final rule. We also proposed 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 regulation 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 proposed 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. 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 proposed 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 proposed to include in a new § 460.120(i)(4) language that provides the PACE organization would still be responsible for all other parts of this section. Section § 460.120(d) specifies the PACE organization must continue to furnish all required services to the participant during the grievance process. We proposed to redesignate current § 460.120(d) as 460.120(j) to account for our other proposals.

We proposed 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 proposed 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 PACE 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 reiterate that accepting and processing a confidential grievance would not negate the PACE organization's responsibilities to investigate and resolve the grievance. It also would not negate the responsibilities to document, aggregate and analyze the grievance, as required under current § 460.120(f). Additionally, 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 proposed 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. 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 in the resolution.

Finally, current § 460.120(f) requires PACE organizations to maintain, aggregate, and analyze information on grievance proceedings. We proposed to redesignate this as paragraph (m) to account for our other proposals. We also proposed 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 the proposed paragraph (l) of this section for purposes of its internal quality improvement program. We noted that this requirement applies to all grievances; oral or written, including anonymous grievances.

We estimated 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 regarding 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 solicited comment on this proposal regarding burden.

We summarize the comments received on the proposal at § 460.120 and provide our responses to those comments in this section of this rule.

Comment: Most commenters expressed their general support for CMS's proposal to clarify the grievance process at § 460.120. A commenter preferred that CMS not formalize the grievance process in regulation, because they believed that establishing specific grievance process requirements in regulation would add to PACE organizations' administrative burden and would divert resources from participant care. Another commenter agreed with formalizing certain aspects of the grievance process but did not want to formalize the grievance process for all complaints, particularly for what the commenter referred to as ''lower-level concerns.''

Response: We thank commenters for their support of formalizing the grievance process at § 460.120. Throughout the years, PACE organizations have expressed interest in a more clearly defined grievance definition, among other process clarifications in the regulation. We do not believe formalizing the grievance process in regulation will be overly burdensome for PACE organizations, as PACE organizations already must process grievances, including evaluating, resolving, responding to, and documenting grievances in a timely manner. Additionally, we included flexibilities in the proposed regulation at § 460.120 when certain conditions are met. For example, PACE organizations may provide oral or written resolution of the grievance, depending on the participant's preference, as specified at the redesignated § 460.120(h)(1). Another flexibility at the redesignated § 460.120(h)(4) allows PACE organizations to 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. We disagree with the commenter's suggestion to categorically exclude certain types of complaints from the formal grievance process at § 460.120. As established at § 460.112(g), each participant has the 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. Specifically, it is a participant's right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the proposed amendments to § 460.120 without modification.

Comment: Most commenters supported CMS's proposed definition of grievance at § 460.120(b), and specifically mentioned their agreement with the part of the proposed definition that describes complaints as grievances regardless of whether remedial action is requested. Many of these commenters, while agreeing with this aspect of the proposed grievance definition at § 460.120(b), generally rejected CMS's consideration of the MA grievance regulations at §§ 422.561 and § 422.564 in the development of PACE grievance requirements. These commenters emphasized the uniqueness of PACE, as an insurer and provider, and recommended that PACE grievance requirements consider the program's uniqueness, rather than repurposing MA grievance regulations for the PACE regulation.

A few commenters disagreed with including complaints for which no remedial action is requested as part of the proposed grievance definition at § 460.120(b). These commenters generally considered the proposed grievance definition at § 460.120(b) to be broader and more administratively burdensome than the current grievance definition at § 460.120, and either did not want to process these complaints as grievances or recommended a separate administrative process for such complaints. A commenter suggested that including complaints for which no remedial action is requested in the grievance definition would increase the number of complaints that would be considered grievances, which the commenter believed would increase the administrative burden of processing grievances without improving participant care and outcomes. The commenter recommended that CMS amend the proposed grievance definition to give PACE organizations the flexibility to not have to document complaints as grievances when the participant declines remediation. The commenter emphasized the uniqueness of the PACE care model and how it requires frequent communication and interaction between staff and participants, which they believed made documenting all complaints as grievances unreasonable and unnecessary. Another commenter indicated CMS's proposed grievance definition emphasized process compliance over staff judgment to the detriment of quality care, participant outcomes, and organizational culture.

Response: We appreciate the commenters' support for the grievance definition proposed at § 460.120(b), including where we specified that complaints can be grievances regardless of whether remedial action is requested. We acknowledge the commenters' general concerns regarding developing

PACE requirements based on MA requirements and agree that there are significant differences between these programs in terms of design and function. We carefully considered the relevance of the MA grievance regulations at §§ 422.561 and § 422.564 as we developed the PACE grievance definition for the December 2022 proposed rule (87 FR 79665). Based on our review of MA grievance regulations, we proposed a PACE grievance definition that includes complaints as grievances regardless of whether remedial action is requested and provides that 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 (87 FR 79665). We have considered commenters' specific feedback on the proposed grievance definition at § 460.120(b) in the responses to comments that follow.

We disagree with the commenters that described the proposed definition of grievance at § 460.120(b) as overly broad, unnecessary, and burdensome with potentially negative consequences for participant care and PACE organizations' workplace culture. As explained in the December 2022 proposed rule, we believe the proposed grievance definition at § 460.120(b) clarifies how we expect PACE organizations to identify grievances. The proposed grievance definition was the result of requests from PACE organizations over the years for CMS to better define grievances in the PACE regulation. We believe the proposed grievance definition clarifies our expectations for grievances and would not necessitate major changes to PACE organizations' existing grievance processes if they are already compliant with the current requirements at § 460.120.

Additionally, we have determined that categorically excluding complaints that do not require remedial action would be counter to compliance with other requirements within the PACE statute and regulation. As established at § 460.112(g), each participant has the 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. Specifically, it is a participant right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by PACE staff. Therefore, amending the regulation to clarify that the definition of grievance includes complaints regardless of whether remedial action was requested provides important guidance to PACE organizations on how to achieve program compliance with current program requirements. Also, PACE organizations are required to aggregate and analyze grievances as part of their quality improvement organization (see §§ 460.120(l) and 460.134(a)(5)). A participant may feel that remedial action is not necessary in a particular situation, but that does not mean the PACE organization should not consider, analyze, and aggregate that information as part of its quality improvement efforts as a whole. If multiple participants have the same complaint, and none of them request remedial action, it may still be indicative of a larger, systemic breakdown that needs to be considered by the PACE organization.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the grievance definition at § 460.120(b) as proposed, which includes complaints regardless of whether remedial action was requested.

Comment: Most commenters disagreed with our proposed inclusion of ''caregiver'' among the list of individuals who can submit a grievance at § 460.120(d). Mostly these commenters expressed concern that the term ''caregiver'' is not defined in the PACE regulation at 42 CFR 460, and recommended that we define, clarify, or provide guidance regarding the term ''caregiver'' so that PACE organizations are not required to include individuals in the grievance process who may not have formal legal authority to act on behalf of the participant. Several of these commenters expressed that allowing a caregiver without formal legal authority to submit grievances on behalf of the participant could influence the participant's care in a way that would not align with the participant's goals, could pose risks to HIPAA Privacy Rule compliance, or may cause confusion when coordinating care for participants with support networks made of many individuals with complex dynamics. Many commenters questioned why it would be necessary for caregivers to have the ability to submit grievances when the participant, participant's family, and participant's designated representatives can already submit grievances per the current requirement at § 460.120(a). One commenter suggested that adding caregivers to the list of individuals who may submit grievances on behalf of participants creates more administrative burden for PACE organizations, because PACE organizations would have to provide and document an increased number of grievance resolution notifications.

Response: We believe that the guidance provided in the December 2022 proposed rule (87 FR 79666) and this response offers adequate clarification of CMS's expectations for PACE organizations regarding how caregivers may participate in the grievance process. As we originally discussed in the January 2021 final rule (86 FR 6018) and reiterated in the December 2022 proposed rule (87 FR 79666), caregivers are typically aware of the participant's situation and are involved in care planning activities, as required at the current § 460.106(e), which states that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. Because caregivers are involved in the care planning process and are presumably providing at least some care to the participant, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant and voice complaints about participant care, regardless of whether these service determination requests or complaints result in changes to the plan of care. Additionally, since caregivers are often the participant's family member and/or designated representative, we do not believe that allowing caregivers to submit grievances on behalf of participants will meaningfully increase burden for PACE organizations, as PACE organizations already must receive, process, and provide notification for grievances submitted by participant family members and/or designated representatives. Also, we reiterate that, as we explained in the January 2021 final rule (86 FR 6018), we have not historically considered ''caregivers'' to include employees or contractors of the PACE organization, though 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. Lastly, we believe that caregiver involvement in the grievance process would benefit, rather than negatively impact, participant care, even when PACE organizations must coordinate within the complexities of participants' support systems. The PACE organization remains responsible for resolving a grievance based on the

facts of the situation and not based on who may have initiated the complaint.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(d) to require that PACE organizations accept grievances from participants' caregivers without modification.

Comment: A commenter requested that we clarify whether the proposed maximum timeframe requirement for notification of a grievance resolution at § 460.120(g)(2) could be satisfied with attempts to notify the individual who submitted the grievance of the resolution within the 3-calendar day maximum timeframe, or whether the individual who submitted the grievance must receive the notification within that timeframe.

Response: We clarify that we would consider the individual who submitted the grievance resolution to be notified for the purposes of § 460.120(g)(2) when the PACE organization furnishes them with the resolution notification within the 3-calendar day maximum timeframe, but as expeditiously as the case requires. However, during a review of PACE organizations' grievance notification documentation, CMS may consider mitigating circumstances based on outreach attempts and when they occurred.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(g)(2) to require that PACE organizations 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) without modification.

Comment: Some commenters recommended a longer timeframe for processing expedited grievances than 24 hours after the time the PACE organization receives the oral or written grievance, as proposed at § 460.120(h). Most of the commenters recommended increasing the maximum timeframe for processing expedited grievances to 72 hours. A commenter recommended that we modify the maximum timeframe to process expedited grievances to require the PACE organization to initiate an investigation within 24 hours, rather than fully resolving the expedited grievance within that timeframe. Another commenter suggested lengthening the maximum timeframe for processing expedited grievances to 2 business days. These commenters all expressed concerns with the possibility that the proposed timeframe at § 460.120(h) would require staff to be available to process grievances at all times, including evenings and weekends, which may burden staff and exacerbate workforce shortages. A commenter suggested that more time may be needed to investigate the grievances at issue to determine if it is imminent or significant and should be processed as an expedited grievance. Most of the commenters expressed their support for allowing PACE organizations the flexibility to determine which grievances could have an imminent and significant impact on the health or safety of participants and should be processed as expedited grievances as proposed at § 460.120(h).

Response: We thank the commenters for their input regarding the proposed expedited grievance requirements at § 460.120(h). After consideration of the concerns raised by commenters, we are declining to finalize our proposal to establish an expedited grievance process at § 460.120(h), and we are redesignating all of our proposed provisions in § 460.120(i) to instead appear at § 460.120(h). While we are not finalizing the expedited grievance process, we remind PACE organizations that they are still required, as 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. Additionally, we emphasize that the IDT is responsible for triaging grievances to determine what needs to be processed more quickly in order to meet the participant's needs. Ultimately, as per § 460.98(a), 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, and PACE organizations must continue to meet this requirement as they process grievances.

Comment: A commenter disagreed with the proposal to establish at § 460.120(i)(1) the requirement that the PACE organization must provide notification of the grievance resolution either orally or in writing based on the individual's preference for notification, with the exception of quality of care grievances as proposed at § 460.120(i)(3). The commenter recommended that all grievance resolution notifications be provided in writing, regardless of the nature of the grievance, as a participant safeguard. Another commenter expressed general support for the flexibility to provide oral or written notice of the grievance resolution as proposed at § 460.120(i)(1).

Response: We thank the commenter for expressing their concern regarding the impact of this provision on participant wellbeing. As discussed in the December 2022 proposed rule (87 FR 79668), we believe that PACE organizations should tailor the grievance resolution notification to the preference of the PACE participant or individual submitting the grievance. Based on our monitoring experience, we believe that requiring all grievance resolutions to be communicated in writing would be unnecessarily burdensome to PACE organizations and would not always be desired by the family members or participants filing the grievance. Therefore, we decline to modify the proposal.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require that PACE organizations must provide notification of the grievance resolution either orally or in writing, based on the individual's preference for notification, without modification, except we are redesignating proposed § 460.120(i)(1) as § 460.120(h)(1).

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(ii) to require PACE organizations to provide the steps taken to investigate the grievance in the grievance resolution notification. The commenters expressed concern that providing the steps taken to investigate the grievance in the notification adds burden to PACE organizations with no additional value to the participant, because detailing the investigation steps is not the same as providing a resolution.

Response: As we stated in the December 2022 proposed rule (87 FR 79668), 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, when an investigation is appropriate, we believe it would be important for the individual who submitted the grievance to understand what the organization found during its investigation. We agree with commenters that the value to the participant is the summary of the findings for each distinct issue, and not the specific steps taken to investigate the grievance.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing this provision by redesignating

§ 460.120(i)(2)(ii) as § 460.120(h)(2)(ii) and modifying § 460.120(h)(2)(ii) to require a summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation, and not requiring that the specific steps taken to investigate the grievance be included in the grievance resolution notification.

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(iii) to require that grievance resolution notifications 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. These commenters noted that PACE organizations do not always know when corrective action will be fully implemented, especially when the corrective action requires a system change to a process within the PACE organization, and they did not believe it would be reasonable for CMS to expect PACE organizations to have all improvements in place and all grievance issues fully resolved in 30 days. Another commenter expressed concern that including corrective actions in the grievance resolution notification could include administrative or human resources actions that are not appropriate to share with participants or their designated representatives and stated that the finalized provision should protect the rights and privacy of participants, clinicians, and staff.

Response: We believe the commenters misunderstood our expectations regarding the proposal at § 460.120(i)(2)(iii). The § 460.120(g) grievance resolution and notification timeframe requirements apply to taking action to resolve the grievance and notifying the individual who submitted the grievance of the grievance resolution. Taking action to resolve the grievance and providing notification does not necessarily require that all corrective actions be completely implemented within the grievance resolution and notification timeframes proposed at § 460.120(g) for all grievances issues.

Additionally, we do not specify the level of detail a PACE organization should provide in the grievance resolution notification to describe the corrective actions taken, or when the participant may expect the corrective action(s) to occur. As explained in the December 2022 proposed rule (87 FR 79668), the purpose of including information on corrective actions that have or will be taken by the PACE organization in response to a grievance is for the participant to understand how their grievance has been resolved or how it will be resolved. PACE organizations may protect provider privacy and business confidentiality in how they disclose the details of their investigation and any corrective action when providing grievance resolution notification. An appropriate level of detail for the corrective action demonstrates that the PACE organization has addressed each specific grievance issue, has taken or will take action to resolve the issue(s), and that the individual submitting the grievance can understand what actions were taken or will be taken to resolve the grievance. For example, if the complaint relates to a participant always being picked up by the PACE driver late, the correction may be that a new driver will be assigned to pick up that participant and the new driver will start in a week.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require the grievance notification to include, for grievances that require 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 without modification, except we are redesignating proposed § 460.120(i)(2)(iii) as § 460.120(h)(2)(iii).

Comment: A commenter disagreed with the proposed requirement to include Quality Improvement Organization (QIO) rights in grievance resolution letters as proposed at § 460.120(i)(3), because they believed modifying standardized grievance notification forms would be administratively burdensome for PACE organizations and they expressed that participants already have many other options available when filing complaints with Medicare.

Response: 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. The fact that there are other ways for participants to file complaints with Medicare has no bearing on participants' right to file quality of care grievances with the QIO. Up to this point, the PACE regulations have been silent as to this right, and the proposed requirement at § 460.120(i)(3) meant to ensure that participants understand and can access this platform for complaints related to quality of care. We would expect PACE organizations to communicate this right to participants, as applicable.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered services without modification, except that we are redesignating § 460.120(i)(3) as § 460.120(h)(3) and paragraphs § 460.120(h)(3)(i) and § 460.120(h)(3)(ii).

Comment: A commenter expressed wanting to better understand CMS's expectations for PACE organizations' cooperation with QIOs regarding quality of care grievances, as well as whether the quality of care grievance requirements we originally proposed at § 460.120(i)(3) (which we redesignate and finalize as § 460.120(h)(3), as noted in the previous response), would apply to Medicaid-only participants.

Response: We appreciate the commenter's interest in learning more about how PACE organizations should participate in the QIO quality of care grievance process, as required by section 1154(a)(14) of the Act and as proposed in the December 2022 proposed rule at § 460.120(i)(3). We will consider future educational opportunities that may help PACE organizations better understand the QIO quality of care grievance process and their role within it.

In the December 2022 proposed rule (87 FR 79668), we explained that 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 proposed 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. We reiterate that the QIO quality of care grievance process applies to Medicare participants' quality of care grievances regarding Medicare covered services. Therefore, participants who are not enrolled in Medicare, including Medicaid-only participants, would not be eligible for the QIO quality of care grievance process.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered

services without modification, except we are redesignating § 460.120(i)(3) as § 460.120(h)(3). Additionally, we are redesignating § 460.120(j) through § 460.120(m) as § 460.120(k) through § 460.120(l) and any redesignated provision citations therein, without further modification.

I. PACE 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 provide 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 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, hereinafter referred to as the April 2010 final rule), which appeared in the April 15, 2010 issue of the **Federal Register**, we 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.''

In contrast to the Part C and D regulations at 42 CFR 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, 4432–33)). However, as explained in the proposed rule, 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. We also believe it is important to ensure there is public transparency regarding a PACE organization that has, or has had, performance and contract compliance deficiencies.

Therefore, we proposed to amend the regulations at 42 CFR 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 4432–33), the disclosure requirement in paragraph (f) did not appear in § 423.128.[258] 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 will serve as an important protection for PACE participants. This policy does not impact the waiver of the remainder of § 423.128 for PACE organizations, as applicable.

We received the following comments on this proposal, which are summarized later in this section:

Comment: Numerous commenters expressed support for this proposal.

Response: We thank the commenters for their support of our proposal, which would enable CMS to require PACE organizations to disclose to current and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS.

Comment: Several commenters suggested that we clarify the scope, mechanism, format, and timing in which we would require PACE organizations to disclose contract and compliance deficiencies to current and potential participants.

Response: We currently anticipate limiting this requirement to situations where we are imposing an intermediate sanction on a PACE organization, and we will follow a disclosure process that is similar to the process in MA and Part D. As in the MA and Part D programs, we would provide PACE organizations with a letter template, and the PACE organization would complete the required information in the template (for example, the bases for the intermediate sanction and participants' rights to a special election period if they have been impacted by the issues identified). We will then review and approve the notification and provide a date for the PACE organization to mail the notice to participants. We will also require the PACE organization to post the notice to its website.

Comment: Several commenters suggested that we clarify the types of contract and performance deficiencies that we might require PACE organizations to disclose to current and potential participants.

Response: As previously discussed, we intend to use these disclosures for instances where we are imposing an intermediate sanction on a PACE organization. We recognize, however, that there may be other instances where

[258] The April 2010 final rule (75 FR 19677) amended § 423.128 to include paragraph (f).

a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or require immediate correction where we believe PACE participants and potential PACE participants should be specifically notified. We may also require disclosures in these instances.

We received a comment on the following topic which is outside the scope of our proposal and to which we are therefore not responding: A request for CMS to create public reporting of performance for PACE organizations similar to Nursing Home Compare and an updated PACE manual with interpretive guidance prior to instituting a disclosure requirement.

After consideration of the comments received, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing our proposal to add § 460.198 to 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, without modification.

J. 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, to comply with the Paperwork Reduction Act of 1995 (Pub L. 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, we proposed to amend paragraph (b) of § 460.202 by striking the final sentence, which states, ''The items collected are specified in the PACE program agreement.'' As explained in the proposed rule, we believe this change would eliminate any confusion regarding where the data collection requirements may be found (87 FR 79673).

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 modifying § 460.202 as proposed would not increase the burden on PACE organizations as they are currently required to furnish information to CMS and the SAA through the aforementioned information collection request.

We solicited comment on this proposal and a summary of the comments received and our response follows.

Comment: A few commenters expressed support of the proposal to amend § 460.202(b) by removing the requirement that the PACE program agreement specify the data to be collected.

Response: We thank commenters for their support. We are finalizing our proposal without modification.

K. Corrective Action (§ 460.194)

Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency (SAA), to conduct comprehensive reviews of PACE organizations' compliance with all significant program requirements. Additionally, sections 18941(e)(6)(A)(i) and 1934(e)(6)(A)(i) of the Act condition the continuation of the PACE program agreement upon timely execution of a corrective action plan if the PACE provider fails to substantially comply with the program requirements as set forth in the Act and regulation. In the 1999 PACE interim final rule, we specified at § 460.194(a) and (c) that PACE organizations must take action to correct deficiencies identified by CMS or the SAA, or PACE organizations may be subject to sanction or termination (84 FR 66296). The 2019 PACE final rule amended § 460.194(a) to expand the ways CMS or the SAA may identify deficiencies that the PACE organization must correct (84 FR 25677). These include ongoing monitoring, reviews, audits, or participant or caregiver complaints, and for any other instance in which CMS or SAA identifies programmatic deficiencies requiring correction (84 FR 25677).

The 1999 PACE interim final rule also specified at § 460.194(b) that CMS or the SAA monitors the effectiveness of PACE organizations' corrective actions. The burden on CMS and SAAs to always monitor the effectiveness of every corrective action taken by the organization after an audit is high, and the number of audits, and thus the number of instances in which monitoring is required, increases each year because the PACE program continues to rapidly grow, and CMS is required to conduct audits in each year of the three-year trial period for new PACE contracts. However, as discussed in the November 2023 proposed rule, our experience overseeing this program has shown that it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited organization. We provided the example that a PACE organization may implement a corrective action that impacts its unscheduled reassessments due to a change in participant status, but historically, these types of assessments are not conducted frequently; thus, it may not be worthwhile for CMS or the states to spend resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor. Additionally, as PACE continues to grow, it will be increasingly important that CMS and the SAA have the flexibility to determine how to use their oversight resources most effectively. Therefore, in the November 2023 proposed rule, we proposed an amendment to § 460.194(b) that specified, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions (88 FR 78587).

As discussed in the November 2023 proposed rule, the flexibility afforded under this proposed amendment to § 460.194(b) would not change our expectation that PACE organizations expeditiously and fully correct any identified deficiencies, and CMS and the SAAs would continue to engage in monitoring efforts that prioritize participant health and safety and program integrity. In addition, as a part

of a PACE organization's oversight compliance program, we require at § 460.63 that PACE organizations adopt and implement effective oversight requirements, which include measures that prevent, detect and correct non-compliance with CMS's program requirements. A PACE organization's oversight compliance program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised. In addition, compliance oversight programs must ensure ongoing compliance with CMS requirements (88 FR 78587).

Since the effect of the proposed change would be to provide CMS and the SAA more flexibility when monitoring the effectiveness of corrective actions without placing new requirements on CMS, the SAAs, 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.

We solicited comment on this proposal. A summary of the comments received, and our response follows.

Comment: Most commenters that addressed the proposed change to § 460.194(b) supported the proposal that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. Some of those commenters, while supportive of the proposal, requested clarification regarding how CMS and the SAA will implement the provision. A few of these commenters offered conditional support for the proposed change at § 460.194(b) based on whether CMS and the SAA's increased discretion when monitoring the effectiveness of corrective actions could lead to increases in burden for PACE organizations, particularly during corrective action plan implementation, monitoring, and release following any issues of non-compliance that CMS or the SAA identify during PACE audits as requiring corrective action. Therefore, these commenters suggested that CMS clarify whether the proposed change at § 460.194(b) could increase burden for PACE organizations. One commenter that supported the proposed change at § 460.194(b) requested clarification regarding any thresholds or criteria that would govern CMS's or the SAA's discretion over corrective action monitoring activities. Another commenter in support of the change at § 460.194(b) recommended that CMS and the SAA ''liberally'' apply their discretion authorities under § 460.194(b) to reduce burden concerns for PACE organizations related to what the commenter considered unnecessary and prolonged monitoring. In reference to the proposed change at § 460.194(b), one commenter stated that they do not support any proposals that reduce the oversight of corrective actions.

Response: We thank commenters for their general support of the proposed change to § 460.194(b), which specifies that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. In response to the one commenter that expressed they do not support any proposals that reduce the oversight of corrective actions, as initially discussed in the November 2023 proposed rule, we reiterate that the proposed change at § 460.194(b) and subsequent discretion afforded to CMS and the SAA regarding the monitoring of the effectiveness of corrective actions would not reduce meaningful oversight of corrective actions (88 FR 78587). Based on our experience overseeing PACE, it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited PACE organization. The example we provided in the November 2023 proposed rule pertained to unscheduled reassessments due to a change in participant status. Historically, these types of assessments are not conducted frequently; therefore, it may not be worthwhile for CMS or the SAA to expend significant resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor (88 FR 78587). CMS and the SAA will implement the flexibility provided by the change at § 460.194(b) such that we safeguard PACE participant wellbeing and safety and program integrity, and effectively adapt to the growing monitoring demands of the program's rapid expansion. Additionally, regardless of the change to § 460.194(b), PACE organizations must continue to comply with all applicable PACE requirements, and CMS and the SAA will continue to oversee PACE organization compliance through a variety of monitoring and oversight activities that ensure accountability.

In response to commenters that support the change to § 460.194(b), we offer the following clarifications. First, we clarify that we do not expect the implementation of the change at § 460.194(b) to alter the PACE audit corrective action monitoring process in a way that increases PACE organizations' burden. Second, we clarify that, given the complexity and scope of potential corrective actions, we decline to establish specific criteria or thresholds as determinants of whether CMS or the SAA will monitor the effectiveness of a particular corrective action for the purposes of this final rule. Moreover, it is important for any corrective action monitoring threshold we create as a result of the discretion afforded under § 460.194(b) to be internal to CMS and the SAA in order to ensure we have the flexibility to reassess any thresholds, as needed, based on new information and changing data. However, such discretion, when applied, will safeguard PACE participant wellbeing and safety and program integrity while considering the monitoring resources available to CMS and the SAA, and will be consistently applied across organizations. Whether monitoring a specific corrective action is necessary or worthwhile will depend on CMS and SAA consideration of these objectives.

In response to the commenter that supported the change at § 460.194(b) and recommended that CMS and the SAA use their corrective action monitoring discretion ''liberally'' to reduce burden for PACE organizations, we emphasize that, although the change to § 460.194(b) might reduce burden for audited PACE organizations, we do not anticipate a significant burden reduction for PACE organizations as a result of this provision. Regardless of formal monitoring of corrective actions by CMS or the SAA, as previously mentioned, PACE organizations must correct any issues of noncompliance identified by CMS and the SAA and adopt their own oversight compliance program in accordance with § 460.63 compliance oversight requirements. Additionally, we expect PACE organizations to demonstrate that they have appropriately corrected all noncompliance identified during their previous audit during subsequent audits by CMS and the SAA.

After consideration of the comments we received, we are finalizing the proposed amendments to § 460.194(b) without modification.

L. Service Determination Requests Pending Initial Plan of Care (§ 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. 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.

The PACE regulations define a service determination request as a request to

initiate a service; 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 (see § 460.121(b)(1)(i)-(iii)). In the January 2021 final rule (86 FR 6024), CMS finalized an exception to the definition of service determination request at § 460.121(b)(2), which, as amended, provides that requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. When CMS proposed this exception in the February 2020 proposed rule, we noted that the exception would apply any time before the initial plan was finalized and discussions among the interdisciplinary team (IDT) ceased (85 FR 9125). We explained that we believed this change would benefit both participants and PACE organizations because it would allow the IDT and the participant and/or caregiver ''to continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes'' (*Id.*). We also stated that ''if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service determination request at that time'' (85 FR 9126).

Our intention for this provision was that the IDT would discuss specific requests made by a participant and/or caregiver as part of the care planning process and determine whether these requests needed to be addressed in the plan of care. We stated in the February 2020 proposed rule that if a participant asked for a specific number of home care hours, that the request would not need to be processed as a service determination request because the IDT was actively considering how many home care hours the participant should receive as part of the development of the initial plan of care (85 FR 9125). This rationale is also consistent with our statement in the proposed rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE),'' which appeared in the August 16, 2016 **Federal Register**, that ''CMS expects 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 that time'' (81 FR 54684).

However, as part of our oversight and monitoring of PACE organizations, we have found that often requests made by participants and/or caregivers prior to the finalizing of the care plan are not discussed during the care planning process and are therefore not considered by the IDT. These requests are some of the first communications from participants related to the care they will be receiving from the PACE organization and would otherwise be considered service determination requests at any other stage of their enrollment. While we continue to believe that it is not prudent for the PACE organization to process these requests as service determination requests, it is important that the IDT consider these requests and determine whether they are necessary for the participant.

Therefore, we proposed to modify the regulation text at § 460.121(b)(2) to specify that service requests made prior to developing the participant's initial plan of care must either be approved and incorporated into the participant's initial plan of care, or the rationale for why it was not approved and incorporated must be documented. Specifically, we proposed to add the following sentence at the end of current § 460.121(b)(2): ''For all requests identified in this section, the interdisciplinary team must (i) document the request, and (ii) discuss the request during the care plan meeting, and either: A) approve the requested service and incorporate it into the participant's initial plan of care, or B) document their rationale for not approving the service in the initial plan of care.'' As we stated in the November 2023 proposed rule at 88 FR 78588, we believe this change is consistent with existing plan of care requirements at § 460.104(b) and aligns with our plan of care proposals in the December 2022 proposed rule (87 FR 79452), which we discuss in section IX.F of this final rule.

As the development of the plan of care is 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 documenting the determination of any assessment of a participant and/or caregiver service request during the initial care planning process is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

We solicited comment on this proposal. A summary of the comments received and our responses follow.

Comment: Most commenters supported our proposal to modify the requirements regarding documenting and responding to requests received prior to the finalization of the initial plan of care.

Response: We thank commenters for their support.

Comment: A couple of commenters requested that the regulation language be modified to clarify that the requirement does not pertain to requests for services made by participants prior to the first day of the participant's enrollment. A commenter opposed the proposed requirement because some States require initial plans of care to be completed prior to enrollment, and the commenter stated it would be inappropriate to process these requests as service determination requests.

Response: We are not persuaded to modify our proposal to clarify that the requirement to document requests for services is only from the time the participant enrolls until the finalization of the initial plan of care. The initial plan of care developed by the IDT is intended to be a comprehensive document that details all necessary services the participant should receive from the PACE organization. As part of that plan of care, the IDT is required to consider the assessments conducted by members of the IDT, but it should also consider the participant's wishes, and any specific requests for services that the participant makes prior to that initial plan of care being developed. The intention of our proposal was to ensure PACE organizations were appropriately addressing participant service requests during the process of creating the initial plan of care regardless of when the requests are received. We would reiterate that we are not asking that the requests for services received prior to the finalization of the initial plan of care be processed as service determination requests as defined in § 460.121(b)(1). As we stated in the November 2023 proposed rule, we do not believe it is appropriate to process these early requests for services as service determination requests (88 FR 78588). However, we further stated in the November 2023 proposed rule that we have seen through our oversight and monitoring activities instances of participants and/or caregivers making requests during the process of creating the initial care plan, which the IDT did not consider (*Id.*).

While we understand that certain service areas may require PACE organizations to finalize the initial plan of care prior to enrollment, we would expect that any request for service received during the initial care planning process would be documented and that the IDT would discuss the request as part of the normal course of creating the initial plan of care regardless of whether the care planning process occurs prior to or after enrollment. We have seen through our oversight and monitoring activities that these requests for services

are typically made by participants during the initial assessment. Therefore, if a PACE organization chooses (or is required by a State) to conduct initial assessments prior to the date of enrollment, we would expect requests made during that time to be documented and considered by the IDT.

Comment: A commenter expressed concern that the documentation requirement was overly burdensome and does not offer any additional value to the participant as PACE organizations are already required to review the care plan with the participant prior to finalization. The same commenter stated that it was more appropriate to begin documenting requests for services after the participant has an initial plan of care to allow the participant time to become familiar with the PACE organization's services.

Response: We are not persuaded by the argument that the requirement to document requests for services received prior to the finalization of the initial plan of care is overly burdensome or that this proposed requirement holds no inherent value to the participant. While we agree that PACE organizations are already required to develop the care plan in collaboration with the participant and/or caregiver prior to finalization, as we stated in the December 2022 proposed rule in our discussion regarding our proposed changes to the plan of care requirements, we have seen instances ''where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving'' (87 FR 79660). We have also seen through oversight and monitoring that each PACE organization develops its own approach concerning the participant's involvement in the care planning process. Although § 460.102(d)(2)(ii) requires the IDT to remain alert to pertinent information about participants, including input that comes from the participants themselves, for many PACE organizations, there is no detailed discussion with the participant. Instead, following the IDT meeting, the PACE organization mails the participant the care plan or other information regarding what services have been included in the care plan. This method of informing the participant of the finalized care plan after the fact does not often allow the participant to make a meaningful contribution to the services being incorporated by the IDT into the initial plan of care. When participants are not able to actively participate in the care planning process, participants may not understand why requested services were not included or considered in the initial plan of care. By documenting the requests for services received during the initial care planning process, the IDT can track the requests to ensure they have addressed all concerns the participant expressed during the initial care planning process and demonstrate to the participant that their concerns were reviewed and considered.

We are also not persuaded by the argument that it is more appropriate to wait until the participant has an initial plan of care to document their requests for services to allow the participant to become more familiar with the services provided by the PACE organization. Per § 460.98(a), PACE organizations are required to provide care that meets participant needs across all care settings, 24 hours a day, every day of the year regardless of whether the participant is familiar with what services are available to them. Additionally, in the early part of a participant's enrollment into PACE, prior to an initial plan of care being finalized, participants are actively engaged in communicating the services they hope to receive from the PACE organization. Those requests that indicate the participant's wishes for treatment should be considered and addressed as part of the development of the initial plan of care. It is the IDT's responsibility to document, assess, and determine whether a requested service is necessary to meet the needs of the participant based on the requirements in § 460.92(b). Due to the PACE benefit including any service that is determined necessary by the IDT, the participant's understanding of the benefit should not hinder their ability to advocate for services they believe are necessary for their medical, physical, social, or emotional needs.

Comment: A commenter supported the proposed changes but requested that we require PACE organizations to inform participants of the formal grievance process for any declined requests. The same commenter requested that we add a requirement for data collection and reporting related to declined requests to identify inequities and systemic issues to hold PACE organizations accountable.

Response: We are not persuaded by the suggestion to modify our proposal to require PACE organizations to discuss the grievance process for any declined requests received prior to the finalization of the initial plan of care. If the IDT reviews a request for a service and decides not to include the request in the initial plan of care, nothing in our proposal would prevent the IDT from explaining the grievance process and providing the participant the right to submit a grievance. However, to the extent that a participant still wants a service that was not included in the initial plan of care, we would expect the PACE organization to process that request as a service determination request and, if the service determination request were denied, to provide appeal rights as detailed in § 460.121(j)(2) and § 460.122. The grievance process would not be the appropriate process if a participant still wanted to advocate for the inclusion of a particular service. The suggestion to require data collection and reporting of declined service requests is beyond the scope of our proposal.

After reviewing and considering the public comments received, we are finalizing the regulation as proposed.

X. 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. 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.

In our December 27, 2022 (CMS–4201–P; RIN 0938–AU96; 87 FR 79452) and November 15, 2023 (CMS–4205–P; RIN 0938–AV24; 88 FR 78476) proposed rules we solicited public comment on each of the aforementioned issues for the following information collection requirements. The following ICRs received PRA-related comment: #2 (Standards for Electronic Prescribing), #7 (Mid-Year Notice of Unused Supplemental Benefits), #9 (Agent Broker Compensation), and #14 (Part D Medication Therapy Management Program Eligibility Criteria). A summary of the comments and our response can be found below under the applicable ICR section.

A. Wage Data

1. Private Sector

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 (*https://www.bls.gov/oes/2022/may/oes_nat.htm*), which, at the time of publication of this final rule, provides May 2022 wages. In this regard, Table J1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

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TABLE J1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Business operations specialists (all others)	13-1199	39.75	39.75	79.50
Compliance officers	13-1041	37.01	37.01	74.02
Computer programmer	15-1251	49.42	49.42	98.84
Healthcare Social workers	21-1022	30.17	30.17	60.34
Marketing Managers	11-2021	76.10	76.10	152.20
Pharmacist	29-1051	62.22	62.22	124.44
Pharmacy Technician	29-2052	19.35	19.35	38.70
Physician all others	29-1229	114.76	114.76	229.52
Registered Nurse*	29-1141	42.80	42.80	85.60
Software and Web Developers, Programmers, Testers	15-1250	60.07	60.07	120.14
Software Developers	15-1252	63.91	63.91	127.82

*The November 2023 NPRM had inadvertently set out "24-1141" as the occupation code for Registered Nurses. The correct code is "29-1141."

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As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

The December 2022 NPRM's (CMS–4201–P) wages were based on BLS' 2021 wage data. This final rule updates those wages to reflect BLS' 2022 wage data. Table J2 compares BLS' May 2021 and May 2022 mean hourly wages for the applicable occupation codes.

The November 2023 NPRM (CMS–4205–P) set out BLS' May 2022 wages. In that regard they are unchanged in this final rule.

TABLE J2: COMPARISON OF 2021 and 2022 MEAN HOURLY WAGES*

Occupation Title	Occupational Code	2021 Mean Hourly Wage ($/hr)	2022 Mean Hourly Wage ($/hr)	Percent Change from 2021 to 2022
Business operations specialists (all others)	13-1199	38.10	39.75	4.33%
Compliance officers	13-1041	36.45	37.01	1.54%
Computer programmer	15-1251	46.46	49.42	6.37%
Healthcare Social workers	21-1022	29.96	30.17	0.7%
Pharmacist	29-1051	60.43	62.22	2.96%
Registered Nurse	29-1141	39.78	42.80	7.59%

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate

an hourly pre-tax wage rate of $24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. There is logic to valuing time spent outside of work, but there is also logic for using a fully loaded wage. In the past, we have used occupational code 00–0000, the average of all occupational codes, which currently is $29.76/hr. Thus we propose a range for enrollees of $20.71/hr–$29.76/hr. Nevertheless, the upper limit is based on an average over all occupations while the lower limit reflects a detailed analysis by ASPE targeted at enrollees many of whom are over 65 and unemployed; consequently, in our primary estimates we will exclusively use the lower limit as we consider it more accurate. However, the effect of using the alternate upper limit will be included in a footnote referenced in Table J7 and the summary table.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this final rule.

1. ICRs Regarding Network Adequacy in Behavioral Health (§ 422.116(b)(2) and (d)(2) and (5))

The following changes will be submitted to OMB for approval under control number 0938–1346 (CMS–10636).

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 one new facility-specialty type that will be subject to network adequacy evaluation under § 422.116. As discussed in the ''Expanding Network Adequacy Requirements for Behavioral Health'' section of the preamble, we are finalizing our proposal to amend the network adequacy requirements and add one combined facility-specialty category called ''Outpatient Behavioral Health'' under § 422.116(b)(2) and to add ''Outpatient Behavioral Health'' to the time and distance requirements at § 422.116(d)(2). For network adequacy evaluation purposes, provider types under this category can include, Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities. Based on the current regulation at § 422.116(e)(2) for all facility-specialty types other than acute inpatient hospitals, the minimum provider number requirement for this proposed new provider type is one. Finally, we also proposed to add the new ''Outpatient Behavioral Health'' facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers 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. To determine the potential burden regarding this proposal, we considered cost estimates for MA organizations to update policies and procedures. However, the burden for updating the HPMS system is a burden to CMS and its contractors and hence is not subject to the requirements of the PRA.

Although there is no cost for MA organizations to report new specialty types to CMS for their network adequacy reviews as this proposal requires, 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 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 3 years for the triennial review. This provision requires that the specialty type 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 type is included. We estimate that it would take 5 minutes (0.0833 hr) at $79.50/hr for a business operations specialist to update policies and procedures related to this task. In aggregate we estimate a one-time burden of 62 hours (742 MA contracts * 0.0833 hr) at a cost of $4,929 (62 hr * $79.50/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is.

3. ICRs Regarding Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

The following 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 this final rule.

In the provision, ''Changes to an Approved Formulary'' (see section III.Q. of the December 2022 proposed rule [87 FR 79452]) we proposed to codify guidance in place since early in the Part D program and in section VII.B.10. of the December 2022 proposed rule (87 FR 79680), we outlined ICRs regarding the proposed provision. In the provision ''Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions'' (see section III.F. of the November 2023 proposed rule [88 FR 78476]), we proposed to update the regulatory text proposed in the December 2022 proposed rule to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as ''maintenance changes'' under § 423.100 as proposed in the December 2022 rule. We also proposed to revise paragraphs (1) and (2) of the § 423.100 definition of ''maintenance changes'' to clarify that certain substitutions need not take place ''at the same time'' but that Part D sponsors can remove or make negative changes to a brand name drug or reference product within a certain time period after adding a corresponding drug or a biosimilar biological product other than an interchangeable biological product to the formulary. Lastly, we proposed a few technical changes, including in support of the above specified proposals. In this final rule, we are finalizing the proposed changes with some technical clarifications that do not impact our estimates.

The burden estimates in the December 2022 proposed rule were based on actual formulary changes submitted to CMS for contract year (CY) 2021 since the ''Changes to an Approved Formulary'' proposals primarily set out to codify existing guidance that Part D sponsors had already been following. We did not make adjustments to the methodology for this collection request

based on the proposal in the November 2023 proposed rule to permit formulary substitutions of a biosimilar biological product other than an interchangeable biological product for the reference product as a maintenance change. New drugs and biological products are approved or licensed by the FDA and become available on the market at irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. Several biosimilar biological products entered the market in 2023,[259] but CMS did not receive any non-maintenance negative change requests from Part D sponsors requesting to apply a negative change to a reference product when adding a corresponding biosimilar biological product to the formulary. It is unclear whether Part D sponsors are not requesting midyear formulary changes due to concerns about patient and provider hesitancy towards biosimilar biological products, or if the current policy that treats such formulary changes as non-maintenance changes disincentivizes Part D sponsors from making midyear formulary changes that will not apply to all enrollees currently taking the reference product. For this final rule, we are revising our burden estimates using the same methodology as the collection request in the December 2022 proposed rule but updated based on actual formulary changes submitted to CMS for CY 2023.

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 annually per Part D contract for a business operations specialist to complete notice requirements to CMS and other specified entities, but this estimate did not include notice to affected enrollees. As discussed later in this section, multiple contracts share the same formulary; therefore, there are efficiencies in managing formularies such that each contract does not assume burden independently. See Table J3 for the burden estimates currently in CMS–10141 that will be removed from the package along with our revised burden estimates. 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) and(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. 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 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 moving 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 2023, CMS approved 542 formularies which were used across 1,556 contracts and 7,048 plans offered by 197 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 2023, 89 parent organizations submitted 2,642 NCRs for 219 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 89 parent organizations, the burden to submit NCRs is estimated to be 220 hours (2,642 NCRs × 0.0833 hr per NCR) at a cost of $ 27,377 ($124.44/hr × 220 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 197 parent organizations representing 542 formularies in 2023. 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, 5,962 formulary submissions (542 formularies × 11 submission windows). We estimate that each formulary file update requires 2 hours to prepare, for a total of 11,924 hours (5,962 submissions × 2 hr per submission) at a cost of $1,483,823 (11,924 hr × $124.44/hr).

In addition to notifying CMS in the manner described, Part D sponsors are required to notify other specified entities of formulary changes. As

[259] Billingsly A. Is There a Biosimilar for Humira? Yes, Here Are 9 Humira Biosimilars Launching in 2023. GoodRxHealth. July 12, 2023. Available from: *https://www.goodrx.com/humira/biosimilars.*

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).* 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 542 formularies in 2023, monthly updates would be posted at least 12 times annually for a total of 6,504 postings (542 formularies × 12 updates/year) by all 197 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 6,504 hours (6,504 updates × 1 hr/update) at a cost of $642,855 ($98.84/hr × 6,504 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 are finalizing our proposal to move this requirement to § 423.120(f)(1) 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. There are no affected enrollees subject to non-maintenance changes since these types of changes are 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 2022 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 in 2023 to the total Medicare Part D enrollment in 2023.

The following example illustrates this process. As of December 2023, there were 52,376,078 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 108 individual plans utilizing this formulary. The total number of Part D enrollees taking Drug A in 2022 was 364,930. The total number of enrollees in the 108 plans implementing the negative formulary change was 1,776,856, representing 3.392 percent of the total Part D enrollment (1,776,856/52,376,078). We then assume that of the 364,930 Part D enrollees taking Drug A during 2022, that 3.392 percent or 12,380 enrollees (364,930 × 0.03392) were affected by the negative formulary change assuming they were still taking the drug in 2023. This logic was applied across all immediate substitutions and maintenance formulary changes submitted for contract year 2023. 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 143 parent organizations that implemented immediate substitutions or maintenance formulary changes for 348 formularies used for 528 contracts and 2,298 plans affecting a total of 54,114 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, envelopes, 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 envelopes:* We assume a cost of $440 for 10,000 envelopes. The cost per envelope is $0.044.
- *Cost of postage:* The current cost of first-class metered mail is $0.64 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 cost per mailing is $0.712 ([$0.007 for paper × 2 pages] + [$0.007 for toner × 2 pages] + $0.64 for postage + $0.044 per envelope). We estimate the total annual mailing cost at $38,529 ($0.7120 per notice × 54,114 affected enrollees).

The summary of burden, labor and non-labor costs, associated with this provision follows in Table J3.

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We received no comments specific to our analysis of paperwork burden based on our proposed changes to an approved formulary in the December 2022

TABLE J3: CHANGES TO AN APPROVED FORMULARY—INCLUDING SUBSTITUTIONS OF BIOSIMILAR BIOLOGICAL PRODUCTS

Regulatory Citation	Response Summary	Total Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
Current Burden to be Removed from Package CMS-10141							
§423.120(b)(5)(i)	Provide Notice of Formulary Change to CMS and Other Specified Entities	(990)	(990)	40	(39,600)	79.50	(3,148,200)
Revised Burden to be Added to Package CMS-10141							
Current Location: §423.120(b)(6)(ii)(A)(*1*) Revised Location: §423.120(e)(1)	Submit Negative Change Request	89	2,642	0.0833	220	124.44	27,377
Current Location: §423.120(b) Revised Location: §423.120(f)	Update Formulary in HPMS	197	5,962	2	11,924	124.44	1,483,823
Current: §423.128(d)(2)(ii)-(iii) Revised Location: No change.	Updating Formulary and Providing Online Notice of Changes on Website	197	6,504	1	6,504	98.84	642,855
Current Location: §423.120(b)(5)(i)(A) and (b)(5)(ii) Revised Location: §423.120(f)(1) and (f)(4)	Direct Written Notice to Affected Enrollees	143	54,114	n/a	n/a	n/a	38,529*
TOTAL		n/a	68,232	Varies	(20,952)	Varies	(955,616)

*Non-labor cost.

proposed rule and the November 2023 proposed rule and are therefore finalizing our estimates based on the proposed methodology but updated with more current data as discussed. In aggregate, our revised estimates result in a reduction of $955,616 and 20,952 hours from the previous annual burden estimates.

4. ICRs Regarding to Improvements to Drug Management Programs (§§ 423.100 and 423.153)

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10874). At this time, the OMB control number has not been determined, but it will be assigned by OMB upon its clearance of our collection of information request. We intend to identify the new control number in the subsequent final rule. The control number's expiration date will be issued by OMB upon its approval of our final rule's collection of information request. When ready, the expiration date can be found on *reginfo.gov.*

Ordinarily, the changes would be submitted to OMB for approval under control number 0938–0964 (CMS–10141), where the current OMB-approved Part D drug management program (DMP) information collection and burden is located. However, based on internal review, we are removing the DMP information collection and related burden from CMS–10141 and submitting it under a new collection of information request (OMB 0938–TBD, CMS–10874). This change will streamline clearance processes and minimize duplicative administrative burden for CMS and other stakeholders. Although we are removing DMP burden from CMS–10141, that collection will continue to include burden associated with many other aspects of the Part D program.

As described in section III.L. Improvements to Drug Management Programs, Definition of Exempted Beneficiary of this final rule, we are amending regulations regarding Part D DMPs for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). Specifically, we are amending the definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain.'' This change will reduce the overall burden associated with sponsors providing DMP case management and notices to potentially at-risk beneficiaries (PARBs) and at-risk beneficiaries (ARBs) because some beneficiaries identified as PARBs under the current definition would be excluded under the amended definition.

Under § 423.153(a), all Part D plan sponsors must have a DMP to address overutilization of FADs for enrollees in their prescription drug benefit plans. Based on 2023 data, there are 319 Part D parent organizations. The provisions codified at § 423.153(f)(2) require that Part D sponsors conduct case management of beneficiaries identified by the minimum overutilization monitoring system (OMS) criteria through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and/or benzodiazepines. Case management must include informing the beneficiary's prescriber(s) of the beneficiary's potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary. Under current CMS regulations at § 423.100, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP.

In 2022, the OMS identified 43,915 PARBs meeting the minimum criteria prior to applying exclusions and 30,411 after excluding exempted beneficiaries. Thus, 13,504 beneficiaries (43,915 − 30,411) met the definition of exempted beneficiary. Amending the definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain'' results in 46 additional enrollees meeting the definition of exempted beneficiary, or 13,550 exempted beneficiaries total (13,504 + 46). This yields 30,365 (43,915 − 13,550) instead of 30,411 beneficiaries requiring case management under the amended definition.

We estimate it takes an average of 5 hours for a sponsor to conduct case management for a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. Of the 5 hours, we assume that 2 hours at $124.44/hr would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.), 2 hours at $38.70/hr would be conducted by a pharmacy technician, and 1 hour at $229.52/hr would be conducted by a physician to work directly with prescribers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $555.80 per PARB case managed ([2 hr × $124.44/hr] + [2 hr * $38.70/hr] + [1 hr * $229.52/hr]). Therefore, the case management team's average hourly wage is $111.16/hr ($555.80/5 hr). In aggregate, we estimate annual burden with the changes for case management is 151,825 hours (30,365 enrollees subject to case management * 5 hr/response) at a cost of $16,876,867 (151,825 hr * $111.16/hr); see case management row in Table J5. CMS 10141 included an estimate for the current case management burden of 178,855 hours and, with the hourly wage updated, a cost of $19,881,522; see case management row in Table J4. Thus, we calculate a savings of 27,030 hours (178,855 hr − 151,825 hr) and $3,004,655 ($19,955,671 − $16,876,867) with this updated burden; see case management row in Table J6 and note that in Table J6 we list savings as a negative number.

As a result of case management, a portion of PARBs may receive notice from a plan sponsor informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Approximately 5 percent of PARBs identified by OMS criteria receive an initial and either a second notice or an alternate second notice. Amending the definition of ''exempted beneficiary'' would reduce the number of notices sent. Therefore, it follows that 2 fewer PARBs would receive notices (46 additional individuals * 0.05) and there would be 4 fewer notices total (2 enrollees * 2 notices/enrollee). Approximately 1,518 (30,365 * 0.05) PARBs overall would receive an initial and second notice (or alternate second notice) annually. We estimate it takes a pharmacy technician at $38.70/hr approximately 5 minutes (0.0833 hr) to send each notice and a total of 10 minutes (0.1667 hr) per enrollee to send both notices. In aggregate, we estimate an annual burden with the changes for sending notices of 253 hours (1,518 enrollees * 0.1667 hr) at a cost of $9,791 (253 hr * $38.70/hr) to send both notices; see the row for notification for enrollees in Table J5. CMS 10141, presenting the current burden, includes an estimated notice burden of 1,319 hours and, with the hourly wage updated, a cost of $51,045; see the row for notification for enrollees in Table J4 Thus, we calculate a savings of 1,066 hours (1,319 hr − 253 hr) and $41,254 ($51,045 − $9,791) with this updated burden; see the row for notification for enrollees in Table J6 and note that in Table J6 we list savings as a negative number.

Amending the definition of ''exempted beneficiary'' also reduces the burden of disclosure of DMP data to CMS based on the outcome of case management of PARBs. Using 30,365

beneficiaries requiring DMP data disclosure, we estimate that it would take (on average) 1 minute (0.0167 hr) at $38.70/hr for a sponsor's pharmacy technician to document the outcome of case management and any applicable coverage limitations in OMS and/or MARx. In aggregate, we estimate an annual burden with the changes for notification to CMS of 507 hours (30,365 PARBs * 0.0167 hr) at a cost of $19,621 (507 hr * $38.70/hr); see the row for notification to CMS in Table J5. CMS–10141, presenting the current burden, includes an estimated data disclosure burden of 597 hours and, with updated hourly wages, a cost of $23,104; see the row for notification to CMS of TableJ4. Thus, we calculate a savings of 90 hours (597 hr − 507 hr) and $3,483 ($23,104 − $19,621) with this updated burden; see the row for notification to CMS in Table J6 and note that in Table J6 we list savings as a negative number.

TABLE J4: CURRENTLY APPROVED BURDEN ESTIMATES WITH UPDATED WAGES

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	306	35,771	5	178,855	111.16	19,881,522
423.153(f)(5-8)	Send Notices (Annualized)	306	7,911	0.1667	1,319	38.70	51,045
423.153(f)(15)	Report to CMS (Annualized)	306	35,771	0.0167	597	38.70	23,104
Total		306	79,453	Varies	180,771	Varies	19,955,671

Table J5 presents the estimated burden in this final rule which will be submitted with the new package, CMS–10874, which uses the currently approved burden from CMS–10141 as a baseline.

TABLE J5: ESTIMATED BURDEN FROM THIS FINAL RULE

Regulatory Citation	Subject	Number of Respondents	Number of Responses (PARBs after exclusions)	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	15,1825	111.16	16,876,867
423.153(f)(5-8)	Send Notices (Annualized)	319	1,518	0.1667	253	38.70	9,791
423.153(f)(15)	Report to CMS (Annualized)	319	30,365	0.0167	507	38.70	19,621
Total		319	62,248	Varies	152,585	Varies	16,906,279

In aggregate, these changes will result in an annual reduction of cost of $3,049,392 and reduction of 28,186 hours. The aggregate burden change (reduction) is presented in Table J6, and will be submitted with the new package, CMS–10874.

TABLE J6: BURDEN CHANGES *

Regulatory Citation	Subject	Number of responses (PARBs after exclusion)	Time per response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	(5,406)	5	(27,030)	111.16	(3,004,655)
423.153(f)(5-8)	Send Notices (annualized)	(6,393)	0.1667	(1,066)	38.70	(41,254)
423.153(f)(15)	Report to CMS (annualized)	(5,406)	0.0167	(90)	38.70	(3,483)
Total		Varies	Varies	(28,186)	Varies	(3,049,392)

* Table J6 is obtained by subtracting from Table J5 (burden of final regulation), Table J4 (current burden). For example, for Case Management, -27,030 hr =151,825 hr - 171,855 hr. Additionally, Table J6 is consistent with the line items in the COI Summary Table.

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

5. ICRs Regarding Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.Q. of this final rule, we discuss two provisions to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS's ability to use and disclose MA encounter data to States for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. This final rule improves access to MA encounter data by:

- Adding ''and Medicaid programs'' to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii); and
- Adding § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to States for the purpose of coordinating care for dually eligible individuals.

Together, these provisions clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). We discuss the regulatory impact on CMS review and fulfillment of new MA encounter data requests in section XI. of this rule, explaining that we did not anticipate any significant impact to CMS.

As discussed in sections III.Q. and XI. of this rule, these provisions will allow States to voluntarily request MA encounter data from CMS for certain allowable purposes to support the Medicaid program. Currently, States can request MA encounter data to support the administration of the Medicare program or Medicare-Medicaid demonstrations, and to conduct evaluations and other analyses to support the Medicare program (including demonstrations). In addition, we interpret the regulation as permitting use and disclosure of MA encounter data for quality review and improvement activities for Medicaid as well as Medicare.

When determining the potential burden on States, we considered our existing data sharing program for States to request Medicare data for initiatives related to their dually eligible population. We expected the process to request MA encounter data would be similar to the process that States currently undertake to request new Medicare FFS claims and events data files or to update allowable data uses. All States, including the District of Columbia, maintain agreements with CMS that cover operational data exchanges related to the Medicare and Medicaid program administration as well as optional data requests for Medicare claims and events data. Therefore, States interested in requesting MA encounter data will not need to complete and submit a new data agreement for MA encounter data; instead, they will submit a use justification for the new data request and update their existing data agreement form. We note that requesting Medicare data is voluntary and that not all States currently request Medicare FFS claims or prescription drug events data for coordinating care of dually eligible beneficiaries, and of those States that request Medicare data, not all States request the same Medicare data files. As with Medicare FFS claims and events data, States will maintain the ability to choose if and when they want to request MA encounter data for existing or newly expanded uses. We further note that the process for States to submit a request for data and for CMS to review these requests are part of standard operations for CMS and many States. Additionally, we have technical assistance support to help States navigate the data request process and maintain their data agreements.

In the August 2014 final rule, when we established several of the current provisions around CMS disclosure of MA encounter data, we explained that we had determined that ''the proposed regulatory amendments would not impose a burden on the entity requesting data files.'' (79 FR 50445). Similarly, for the proposed refinements to the approved data uses and the data disclosure in the November 2023 proposed rule, we did not anticipate a significant change in burden for States.

In the November 2023 proposed rule, we solicited comments specific to our analysis of no impact on paperwork burden. We received no comments on this analysis. We are finalizing the ICR narrative as is.

6. ICRs Regarding Standards for Determining Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (§ 422.102(f)(3)(iii) and (iv) and (f)(4))

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As explained in section IV.B. of this rule, due to increased offering of SSCBI, we are finalizing our proposal with modification to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of ''relevant acceptable evidence'' related to the item or service the MA

organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations, and prohibit plans from modifying policies like utilization management requirements, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations; (3) require the MA plan to document SSBCI eligibility determinations, including approvals and denials; and (4) codify CMS's authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. We now estimate burden.

Item (4) is a burden specific to CMS and is therefore not subject to collection of information requirements. We choose to combine the burdens of: (1) and (2) as the evidence gathered under (1) will likely directly inform the criteria established under (2).

In estimating the impact, we note the following: (i) Not all contracts offer SSBCI (only about 40 percent); (ii) not all plan benefit packages (PBP) offer them (only about 20 percent); (iii) the distribution of the number of SSBCI per PBP is highly skewed (for example, for 2023 the average is about 8 while the median is 2); and (iv) both the median and 3rd quartile of the number of SSBCI per PBP reflect only a handful of SSBCI offered.

Based on internal CMS data we are using 10,000 SSBCI per year for the three-year estimates required by the Collection of Information requirements. To comply with the requirements of the provision that would require bibliography, a staff member knowledgeable in health should be deployed. We are using a registered nurse. Establishing a bibliography requires research, including reading papers and assessing their quality. Because the bibliography would contain only citations and copies of the necessary information, and not any narrative, we assume these activities would take a day of work (8 hours), which can refer to the aggregate activity of 1 nurse working 8 hours or 2 nurses working 4 hours each. A plan would need to review and update its bibliography annually. We assume that updating an existing bibliography would take less time than establishing an initial bibliography. We estimate that it would take 8 hours each year to update existing bibliographies.

To create a single line-item, we estimate that it would take 8 hours at $85.60/hr for a registered nurse to create the bibliography for one plan. Thus, the median burden per plan is 16 hours (8/hr per SSBCI * a median of 2 SSBCI) at a cost of $1,397 ($85.60/hr *16 hr). The aggregate cost across all plans would be 80,000 hours (8 hours per SSBCI * 10,000 aggregate SSBCI) at a cost of $6,848,000 (80,000 * $85.60/hr).

Regarding the requirement for plans to document approvals and denials of SSCBI eligibility, it is reasonable that plans already have this information stored in their systems. Thus, we assume that plans will need to compile data already collected into a report or other transmittable format. We estimate that it would take 2 hours at $98.84/hr for a programmer to complete the initial software update. In aggregate, we estimate a one-time burden of 1,548 hours (774 plans × 2 hr) at a cost of $153,004 (1,548 hr × $98.84/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

7. ICRs Regarding Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111 and 422.2267)

When ready, the following changes will be posted for public review under control number 0938–TBD (CMS–10893) 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 after the publication of this final rule and when the model notice has been completed. In the meantime, we are scoring the burden to identify the expected PRA-related costs. At this time, the OMB control number has not been determined, but it will be assigned by OMB upon its approval of our new collection of information request.

We note that in the proposed rule, we stated that the changes would be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). However, because (as discussed in the preamble) we intend to create a model notice which will require additional burden analysis and scoring, CMS believes providing the additional 60-day and 30-day public notices through a standalone PRA package will allow both the agency and stakeholders to give the model notice more comprehensive and thoughtful consideration.

Per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS's annual PBP reviews. At the same time, CMS has received reports that MA organizations have observed low utilization for many of these benefits by their enrollees and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees. The finalization of this new requirement will establish a minimum requirement for MA organizations to conduct outreach to enrollees to encourage utilization of supplemental benefits.

We have several concerns about this low utilization of some supplemental benefits. First, we are concerned that beneficiaries may be making enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP), but once enrolled in the plan the beneficiaries do not fully utilize, or utilize at all, those supplemental benefits during the plan year. Such under-utilization of supplemental benefits may hinder or nullify any potential health benefit value offered by these extra benefits. Additionally, section 1854(b)(1)(C) of the Act requires MA plans to provide the value of the MA rebates to enrollees; per CMS regulations at § 422.266, MA rebates must be provided to enrollees in the form of payment for supplemental benefits (including reductions in cost sharing for Part A and B benefits compared to Original Medicare), or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that the MA rebate is provided to enrollees in a way that they can benefit from the value of these rebate dollars.

Hence, we are finalizing the proposal to require plans engage in targeted outreach to inform enrollees of their unused supplemental benefits they have not yet accessed. This targeted outreach aims to increase utilization of these benefits, as it would increase enrollees' awareness of the supplemental benefits available to them.

This new requirement will ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plans they have not yet accessed. Beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the

plan year, to each enrollee with information pertaining to each supplemental benefit available through the plan year that the enrollee has not accessed, by June 30 of the plan year. For each covered mandatory supplemental benefit and optional supplemental benefit (if elected) the enrollee is eligible for but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in the Evidence of Coverage (EOC). For SSBCI, the notice must also include the proposed new SSBCI disclaimer. Finally, all notices must include the scope of the supplemental benefit(s), applicable cost-sharing, instructions on how to access the benefit(s), applicable information on use of any network providers application information for each available benefit consistent with the format of the EOC, and a toll-free customer service number and, as required, corresponding TTY number to call if additional help is needed.

When estimating the burden of this provision, we first noted that plans already keep track of utilization patterns of benefits by enrollees. The primary burden is therefore dissemination of notices. In this regard, there are three burdens: (1) a one-time update to software systems to produce reports; (2) a one-time update of policies and procedures; and (3) the printing and sending of notices to beneficiaries.

- We estimate that a software developer working at $127.82/hr would take about 4 hours to update systems. In aggregate we estimate a one-time burden of 3,096 hours (774 prepaid contracts * 4 hr/contract) at a cost of $395,731 (3,096 hr * $127.82/hr).
- We estimate that a business operations specialist working at $79.50/hr would take 1 hour to update of policies and procedures. In aggregate we estimate a one-time burden of 774 hours (774 prepaid contracts * 1 hour/contract) at a cost of $61,533 (774 hr * $79.50/hr).
- The major cost would be printing and dissemination. There have been several recent CMS rules in which such printing and dissemination has been estimated.

A recent estimate was presented in proposed rule, ''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,'' CMS–4201–P, (87 FR 79452) published on December 27, 2022. We have checked the prices listed there for paper and toner and found them consistent with current pricing.

- *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:* As a result of comments discussed in detail at the end of this ICR we are revising our estimate of cost of postage to $0.64, the cost of 1st class metered postage for the first ounce per enrollee. The mailings have personally identifiable information necessitating first class mailings.
- *Cost of envelopes:* Because we are not using bulk mailings, we require envelopes. Accordingly, 10,000 envelopes cost approximately $440, resulting in a cost per envelope of $0.044.

To make a final calculation we need to estimate the number of enrollees affected and the average number of pages involved.

We believe it reasonable that every MA enrollee has at least one supplemental benefit that they have not used. Since PDPs do not provide supplemental benefits, we would require 32 million mailings for the 32 million enrollees in prepaid contracts. We do not have a definite basis for estimating the average number of pages needed per enrollee. Some enrollees may only require 1 page listing 1 to 3 benefits with all information required by CMS. Some enrollees may require more. We are estimating 3 pages on average per enrollee. Consistent with a 3-page average we are not estimating extra postage (extra postage would first be required for mailings of seven or more pages and we have no way of estimating how many plans if any would require an excess of 6 pages).

Therefore, costs per mailing are $0.726 per mailing ([3 * $0.007 for paper] + [3 * $0.007 for toner] + $0.64 for postage + $0.044 for an envelope). The aggregate non-labor cost for 32 million mailings of one page would be $23,232,000 (32,000,000 * $0.726).

We received the following comment:

Comment: For various reasons, some commenters believed CMS underestimated the costs associated with printing and mailing documents that consist of personalized information; for example, a commenter stated their printing costs were always higher for personalized materials; some commenters estimated average document lengths would be much higher than the CMS estimate, from 18 to over 20 pages.

Response: With regard to the cost of mailing, we thank the commenters for pointing out the increased cost for mailing personalized materials and agree. Therefore, we revised mailing costs to reflect first order postage and the cost of envelopes versus bulk mailing consistent with HIPAA requirements.

With regard to length, the Mid-Year Notice of Unused Supplemental Benefits is intended to be a concise and user-friendly document, and CMS is committed to the formulation of a model design that is both informative and succinct. The length of the document will ultimately vary from enrollee to enrollee, depending on individual utilization and the number of supplemental benefits offered under the plan.

8. ICRs Regarding New Requirements for the Utilization Management Committee (§ 422.137)

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

As discussed in section IV.F. of this rule, we are adding new requirements related to the Utilization Management (UM) Committee established at § 422.137.

We are finalizing at § 422.137(c)(5) to require a member of the UM committee have expertise in health equity. Reviewing UM policies and procedures is an important beneficiary protection, and adding a committee member with expertise in health equity will ensure that policies and procedures are reviewed from a health equity perspective. We estimate that a compliance officer working at $74.02/hr would take 30 minutes for a one-time update of the policies and procedures. In aggregate, we estimate a one-time burden of 483 hours (966 plans * 0.5 hr) at a cost of $35,752 (483 hr * $74.02/hr).

We are finalizing at § 422.137(d)(6) to require the UM committee to conduct an annual health equity analysis of the use of prior authorization and publicly post the results of the analysis to the plan's website. The analysis will examine the impact of prior authorization, at the plan level, on enrollees with one or more of the following social risk factors: (i) receipt of the low-income subsidy for Medicare Part D, or being dually eligible for Medicare and Medicaid, or (ii) having a disability, as reflected in CMS's records regarding the basis for Medicare Part A entitlement. To gain a deeper understanding of the impact of prior authorization practices on

enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. The metrics that must be stratified and aggregated for all items and services for this analysis are as follows:

- The percentage of standard prior authorization requests that were approved.
- The percentage of standard prior authorization requests that were denied.
- The percentage of standard prior authorization requests that were approved after appeal.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved.
- The percentage of expedited prior authorization requests that were approved.
- The percentage of expedited prior authorization requests that were denied.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations.

We estimate that a software and web developer working at an hourly wage of $120.14/hr would take 8 hours at a cost of $961 (8 hr * $120.14/hr) for developing the software necessary to collect and aggregate the health equity analysis data required to produce the report. In aggregate, we estimate a one-time burden of 7,728 hr (966 plans * 8 hr/plan) at a cost of $928,442 (7,728 hr * $120.14/hr).

Annually, the report must be produced and posted to the plan's website. The health equity analysis and public reporting must be easily accessible, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); to automated searches and direct file downloads through a link posted in the footer on the plan's publicly available website, and includes a txt file in the root directory that includes a direct link to the machine-readable file of public reporting and health equity analysis to establish and maintain automated access. We believe that making this information more easily accessible to automated searches and data pulls and capturing this information in a meaningful way across MA organizations will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information. We assume the plans' programmers will make this an automated process accessing data already in the plans' systems; hence, we estimate minimal time to produce and inspect the report prior to posting. We estimate a Business Operations Specialist working at $79.50/hr would take 0.1667 hr (10 minutes) to produce, inspect, and post the report at a cost of $13 ($79.50/hr * 0.1667 hr). In the aggregate, we estimate an annual burden of 161 hours (966 plans * 0.1667 hr/plan) at a cost of $12,800 (161 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

9. ICRs Regarding Agent Broker Compensation (§ 422.2274)

Since we are scoring this provision as having no burden, we are not submitting any changes to OMB. The active requirements and burden estimates are approved by OMB under control number 0938–0753 (CMS–R–267).

Currently, agents and brokers are compensated by MA plans at national fair market value (FMV) base rate a base rate with a maximum of $611 per enrollee, plus administrative payments. As explained in section X.X of this finalized rule, separate administrative payments are being eliminated but the base rate per enrollee is increasing by $100 per enrollee for new enrollments in MA plans, beginning with contract year 2025. We are also eliminating administrative payments for PDPs and increasing their base rate by $100. For each renewal, agents and brokers receive compensation equal up to 50 percent of the compensation rate so that for MA and PDP enrollees' agents and brokers would receive up to $50 more per enrollee renewal, as permitted under § 422.2274(d)(3).

These increases of $100 per enrollee for MA plan enrollment, and up to $50 for renewals of MA and PDP plans are not costs but rather transfers. The money that formerly was being paid for administrative is sufficient to cover these increases. While we do not have detailed quantitative information on payments, many commenters, from both those who pay as well as those who receive, submitted overall quantitative payment recommendations for administrative payments. The numbers range from $50 to about $500. In other words, currently, several hundred dollars is already being paid per enrollee for administrative payments; this finalized regulation, requiring a payment of $100 per new enrollment would not, according to most commentators, increase net payments but transfer a portion of them to increased compensation.

The differences between this finalized version and the proposed version are explained below in our response to comments.

Comment: Many commenters provided feedback on our estimates for administrative costs in the proposed rule. These comments were both purely qualitative (for example, too low), semi-qualitative (for example, the variance and volatility of the estimates preclude using one number), and quantitative with a wide range of $50 to $500 per enrollee. Comments were submitted by individuals and organizations that that both receive these payments as well as those that make payments.

The comments also included a variety of line items besides the training and transcription items discussed in the NPRM, which commenters believed should be included in estimating the minimum necessary cost of administrative activities.

Response: We thank the commenters for their detailed observations. After careful consideration of these comments several changes were made from the NPRM. We adopted a total cost approach in the Final Rule versus the line-item-approach used in the NPRM. Generally, line-item approaches are appropriate when variability is small and detailed quantitative information is available. This is not the case for agent-brokers and therefore we adopted a total cost approach. We used the wide range of total costs supplied by the commenters. The reasons for adopting the $100 total cost are detailed in section X.X of the preamble. Our basic goals were to provide sufficient funds so that payments for legitimate MA and PDP enrollment could be made while excessive funding being used for other purposes was not encouraged. Because the current administrative payments rates are estimated to be significantly higher than the flat $100 increase to encompass these administrative payments, we have classified this $100 payment as a transfer rather than as a new cost.

As a result of comments, we are finalizing our impact analysis as a transfer with no additional cost.

10. ICRs Regarding Rationales for an Exception From the Network Adequacy Requirements (§ 422.116(b) Through (e))

The following changes will be submitted to OMB for approval under

control number 0938–1346 (CMS–10636).

Historically, the industry has stated that CMS's current network adequacy criteria under § 422.116 create challenges for facility-based Institutional Special Needs Plans (I–SNP) because facility-based I–SNP enrollees access services and seek care in a different way than enrollees of other plan types. Thus, we are finalizing provisions to broaden our acceptable rationales for facility-based I–SNPs when submitting a network exception under § 422.116(f). The first new basis for an exception request is that a facility-based I–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care. Facility-based I–SNPs may also request an exception from the network adequacy requirements in § 422.116(b) through (e) if: The I–SNP covers Additional Telehealth Benefits (ATBs) consistent with § 422.135 and uses ATB telehealth providers of the specialties listed in paragraph (d)(5) to furnish services to enrollees; when substituting ATB telehealth providers of the specialties listed in paragraph (d)(5) for in-person providers, the facility-based I–SNP would fulfill the network adequacy requirements in § 422.116(b) through (e); the I–SNP complies with § 422.135(c)(1) and (2) by covering in-person services from an out-of-network provider at in-network cost sharing for the enrollee who requests in-person services instead of ATBs; and the I–SNP provides substantial and credible evidence that the enrollees of the facility-based I–SNP receive sufficient and adequate access to all covered benefits.

To determine the potential burden, we considered the one-time burden for MA organizations to update policies. The other burden associated with this provision involve updates to the HPMS system, which is done by CMS and its contractors and hence is not subject to the requirements of the PRA.

MA organizations that offer facility-based I–SNPs are already required to conduct work related to network adequacy reviews that happen during the initial or service area expansion application process, or every 3 years for the triennial review. Further, MA organizations that offer facility-based I–SNPs should already have measures in place to submit data to meet CMS network adequacy review requirements to CMS, so there is no additional burden.

We understand that MA organizations will need to update their policies and procedures related to broadening our acceptable rationales for facility-based I–SNPs when submitting a network exception. We estimate that a business operations specialist working at $79.50/hr would take 5 minutes (0.0833 hr) to update policies and procedures related to this task. In aggregate, we estimate a one-time burden of 0.8 hour (10 facility-based I–SNP contracts * 0.0833 hr) at a cost of $64 (0.8 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

11. ICRs Regarding Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

a. MA Plan Requirements and Burden

In section VIII.F. of this final rule, we are amending §§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c). Section 422.514(h) will require an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, where that MA organization offers a D–SNP (and that parent organization also contracts with the State as a Medicaid managed care organization (MCO) in the same service area), to only offer one D–SNP for full-benefit dually eligible individuals. We are finalizing the regulation at § 422.514(h) with a minor technical modification at § 422.514(h)(1) to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposal at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with technical modifications our proposed amendment at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accepts new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). This finalized provision will also require the affected D–SNP to limit new enrollment to individuals enrolling in, or in the process of enrolling in, the affiliated Medicaid MCO effective 2027, and further require the D–SNP to limit all enrollment to individuals enrolled in, or in the process of enrolling in the affiliated MCO effective 2030. A new contract provision that we are finalizing at § 422.503(b)(8) will prohibit parent organizations from offering a new D–SNP when that D–SNP would result in noncompliance with the regulation finalized at § 422.514(h). Additionally, the finalized regulation at § 422.504(a)(20) will require compliance with § 422.514(h). To support parent organizations seeking to consolidate D–SNPs, we are also finalizing § 422.530(c)(4)(iii) that will provide a new crosswalk exception to allow D–SNP parent organizations to crosswalk enrollees (within the same parent organization and among consistent plan types) where they are impacted by the requirements at § 422.514(h).

The provisions we are finalizing at §§ 422.514(h) and 422.530(c)(4)(iii) will create burden for MA organizations where they offer multiple D–SNPs in a service area with a Medicaid MCO. Impacted MA organizations will need to non-renew or (more likely) combine plans and update systems as well as notify enrollees of plan changes. We expect that MA organizations will need two software engineers with each working 4 hours at $127.82/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at $79.50/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2027) of 600 hours (50 plans * 12 hr/plan) at a cost of $67,028 (50 plans × [(8 hr * $127.82/hr) + (4 hr * $79.50/hr)]). The aforementioned changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

We are finalizing a proposal to redesignate § 423.38(c)(35) as § 423.38(c)(36) and finalizing with modification a new integrated care special enrollment period (SEP) at § 423.38(c)(35). This final policy narrows the scope from the proposed policy that would have allowed enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans. Instead, the integrated care SEP that we are finalizing at § 423.38(c)(35) will only be available to facilitate aligned enrollment as defined at § 422.2 and are clarifying in § 423.38(c)(35)(i) that the SEP is available only for full-benefit dual eligible individuals as defined in § 423.772. The integrated care SEP at § 423.38(c)(35) will require plans to update guidance and train staff. That new burden would be limited to FIDE SNPs, HIDE SNPs, and AIPs. We expect that plans will need one software engineer working 4 hours at $127.82/hr to update software and one business operations specialist working 4 hours at $79.50/hr to update plan policies and procedures and train staff in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2025) of 904 hours (113 plans * 8 hr/plan) at a cost of $93,709 (113 plans × [(4 hr * $127.82/hr) + (4 hr * $79.50/hr)]). We do not anticipate any new burden to plans after the initial year. The aforementioned changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

b. Medicare Enrollee Requirements and Burden

At § 423.38(c)(4) we are replacing the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP. At § 423.38(c)(35), we proposed a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis and are finalizing this proposal with a modification that will narrow the scope of the SEP.

The amendments we are finalizing at § 423.38(c)(4) and (35) will affect the circumstances in which individuals can change plans. Individuals can complete an enrollment form to effectuate such changes, and we have previously estimated that the forms take 0.3333 hours (20 min) to complete as cited under OMB control number 0938–1378 (CMS–10718). However, Medicare beneficiaries make enrollment choices currently, and we do not expect the overall volume of enrollment selections to materially change with our finalized provisions. Therefore, we do not believe the provisions at § 423.38(c)(4) and (35) will impact the burden estimates that are currently approved under 0938–1378 (CMS–10718). Similarly, we are not finalizing any changes to that collection's currently approved forms.

In section XI. of this rule, we describe the impacts related to the expected enrollment shift from non-integrated MA–PDs into FIDE SNPs, HIDE SNPs, and AIPs over time as more D–SNPs align with Medicaid MCOs.

12. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267) consistent with burden on MA plans identified as D–SNP look-alikes under § 422.514(d) through (e). While mentioned below, we are not making any changes under control number 0938–0935 (CMS–10237) and control number 0938–1051 (CMS–10260).

As described in section VIII.J. of this final rule, we are reducing the D–SNP look-alike threshold from 80 percent to 60 percent over a two-year period. We are finalizing a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for CY 2025. For CY 2026, we are reducing the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach will minimize disruptions to dually eligible individuals and allow plans and CMS to operationalize these transitions over a two-year period.

We will maintain processes to minimize disruption for the enrollees in plans affected by this change. We are applying the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the D–SNP look-alike contracting limitation of 70 percent or greater dually eligible individuals effective plan year 2025 and 60 percent or greater dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D–SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures will help to minimize disruption for current enrollees as a result of the prohibition on contract renewal for existing D–SNP look-alikes. For plan year 2027 and subsequent years, we are limiting the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Based on our experience with D–SNP look-alike transitions through plan year 2024, the vast majority of enrollees transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike.

MA organizations can utilize other CMS processes to transition D–SNP look-alike enrollees to other MA plans. For example, an MA organization can utilize the CMS crosswalk process if it is transitioning the full D–SNP look-alike enrollment to one non-SNP plan benefit package (PBP) of the same type offered by the same MA organization under the same contract and the requirements at § 422.530 for a crosswalk are met. An MA organization moving the entire enrollment of the D–SNP look-alike PBP to another PBP of the same type under the same contract may structure this action as a consolidation of PBPs and use the crosswalk for consolidated renewal process, under § 422.530(b)(1)(ii). An MA organization may utilize the crosswalk exception process, subject to CMS approval, at § 422.530(c)(2) to transition the entire enrollment of the MA contract (including the D–SNP look-alike) to another MA contract (of the same type) offered by another MA organization with the same parent organization as part of a contract consolidation of separate MA contracts. While multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees to D–SNPs.

Using data from the 2023 contract year, we estimate that there are 30 non-SNP MA plans that have enrollment of dually eligible individuals of 70 percent through 79.9 percent of total enrollment and 40 non-SNP MA plans that have enrollment of dually eligible individuals of 60 percent through 69.9 percent of total enrollment. As of January 2023, the 30 non-SNP MA plans had total enrollment of 53,334 enrollees and the 40 non-SNP MA plans had 92,100 enrollees collectively. Of the 30 non-SNP MA plans with 70–79.9 percent dually eligible enrollment, 28 are in States where for contract year 2023 there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). Of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment, all are in States where for contract year 2023 there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). As of January 2023, these 68 plans had total enrollment of 145,434 for contract year 2023. If these plans all have the same

enrollment pattern in 2024, MA organizations will need to non-renew for plan year 2025 those 28 plans that exceed the criteria we are finalizing in this rulemaking to lower the threshold to 70 percent for plan year 2025. Similarly, MA organizations with plans that exceed the criteria we are finalizing in this rulemaking to lower the threshold to 60 percent for plan year 2026 would need to non-renew 40 plans for plan year 2026. Each MA organization will have the opportunity to make an informed decision to transition enrollees into another MA–PD plan (offered by it or by its parent organization) by: (1) identifying, or applying, or contracting for, a qualified MA–PD plan, including a D–SNP, in the same service area; or (2) creating a new D–SNP through the annual bid submission process. Consistent with our experience with D–SNP look-alikes non-renewing for plan years 2021 through 2024, we expect the vast majority of D–SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D–SNP look-alike, and we expect in rare instances that the non-renewing plan may choose to not transition enrollees. In plan year 2023, 9 of the 47 D–SNP look-alikes transitioned approximately 3,300 enrollees to Traditional Medicare, which accounted for less than 2 percent of total enrollees transitioned from D–SNP look-alikes. In plan year 2024, 3 of the 12 D–SNP look-alikes transitioned approximately 1,414 enrollees to Traditional Medicare, which accounted for 7 percent of total enrollees transitioned from D–SNP look-alikes. The changes required of MA organizations based on this rule will impact D–SNP look-alikes and their enrollees (see section VIII.J. of this final rule). While we cannot predict the actions of each affected MA organization with 100 percent certainty, we base our burden estimates on the current landscape of D–SNP look-alikes and our experience with transitions of D–SNP look-alikes through plan year 2024.

a. MA Plan Requirements and Burden

As indicated, the following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

At § 422.514(e), we established a process for an MA organization with a D–SNP look-alike to transition individuals who are enrolled in its D–SNP look-alike to another MA–PD plan offered by the MA organization, or by the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. This process allows, but does not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and other qualifying MA–PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form. This transition process is conceptually similar to the ''crosswalk exception'' procedures at § 422.530(a) and (b); however, § 422.514(e) allows the transition process to apply across contracts or legal entities and from non-SNP to SNPs provided that the receiving plan is otherwise of the same plan type (for example, HMO or PPO) as the D–SNP look-alike.

Based on the experience of D–SNP look-alike transitions through plan year 2024, we believe 94 percent of D–SNP look-alikes for plan years 2025 and 2026 will be able to move enrollees into another MA–PD plan using the transition process established at § 422.514(e) or existing crosswalk functionality at § 422.530 and will choose to transition enrollment for plan years 2025 and 2026. All are in States where for contract year 2023 there are D–SNPs or comparable managed care plans that would be subject to § 422.514(d). Therefore, we are assuming the burden of 26 of the 28 non-SNP MA plans with 70–79.9 percent dually eligible enrollment and offered in a State with a D–SNP would transition enrollees for plan year 2025 (for a January 2025 effective date) and 38 of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment would transition enrollees for plan year 2026 (for a January 2026 effective date). In 2027 and subsequent years, we estimate that 12 plans per year would be identified as D–SNP look-alikes under § 422.514(d). Consistent with our assumptions for plan years 2025 and 2026, we assume 94 percent of D–SNP look-alikes for plan year 2027, which is 11 D–SNP look-alikes, will be able to move enrollees into another MA–PD plan. Consistent with our estimates from the June 2020 final rule, we estimate each plan will take a one-time amount of 2 hours at $79.50/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D–SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP because they would not need to verify enrollees' Medicaid eligibility. The 2-hour time estimate accounts for any additional work to confirm enrollees' Medicaid eligibility for D–SNP lookalikes transitioning eligible enrollees to a D–SNP. Based on the previous discussion, the estimates for the burden for MA organizations to transition enrollees to other MA–PD plans during the 2025–2027 plan years is summarized in Table J7.

TABLE J7: BURDEN FOR TRANSITIONING D-SNP LOOK-ALIKE ENROLLEES INTO ANOTHER MA-PD (FOR YEARS 2025–2027)

Year	Number of Plans	Time per Response (hr)	Total Time (hr)	Total Cost (using $79.50/hr for a business operations specialist) ($)
2025	26	2	52	4,134
2026	38	2	76	6,042
2027	11	2	22	1,749
Total	75	6	150	11,925
Average	25 (75/3)	2 (6/3)	50 (150/3)	3,975 (11925/3)

Based on our experience through plan year 2024, we expect the vast majority of MA organizations with non-SNP MA plans with dually eligible enrollment between 60 and 80 percent of total enrollment also have an MA–PD plan with a premium of $0 or a D–SNP in the same service area as the D–SNP look-alike. Based on 2023 plan year data, of the 30 non-SNP MA plans with 70 to 79.9 percent dually eligible enrollment, 19 of these plans (63 percent) have a D–SNP within the same service area or nearly the same service area. Also based on 2023 plan year data, of the 40 non-SNP MA plans with 60 to 69.9 percent dually eligible enrollment, 24 of these plans (60 percent) have a D–SNP within the same service area or nearly the same service area. An MA organization with one of these non-SNP MA plans could expand its service area for an existing MA–PD plan or D–SNP. The MA organizations with the non-SNP MA plans between 60 and 79.9 percent dually eligible enrollment already have the opportunity to establish a D–SNP and expand their service areas. Any burden associated with these MA organizations establishing new D–SNPs and/or expanding their service areas is already captured under currently approved burden under control number 0938–0935 (CMS–10237) for creating a new MA–PD plan to receive non-SNP MA plan enrollees. In this regard, we are not making any changes under that control number.

Per § 422.514(e)(2)(ii), in the Annual Notice of Change (ANOC) that the MA organization must send consistent with § 422.111(a), (d), and (e), the MA organization will be required to describe changes to the MA–PD plan benefits and provide information about the MA–PD plan into which the individual is enrolled.

Consistent with § 422.111(d)(2), enrollees will receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first date of the annual election period (AEP). As each MA plan must send out the ANOC to all enrollees annually, we do not estimate that MA organizations will incur additional burden for transitioned enrollees. The current burden for the ANOC is approved by OMB under control number 0938–1051 (CMS–10260). In this regard, we are not making any changes under that control number.

We expect one plan for plan year 2025 and two plans for plan year 2026 will be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at § 422.514(e)(4), as we anticipate—based on our experience with transitions through plan year 2024—not all D–SNP look-alikes will be able to transition their enrollees into another MA–PD plan (or plans).

b. Enrollee Requirements and Burden

In 2027 and subsequent years, we estimate that 12 plans per year would be identified as D–SNP look-alikes under § 422.514(d). We base our estimate on the fact that there are 12 D–SNP look-alikes for plan year 2024, which is the first year following the phase in of the 80-percent threshold. We expect the policy we are finalizing in this rule to lower the threshold for identifying D–SNP look-alikes from 80 percent to 60 percent will increase the number of plans identified as D–SNP look-alikes. However, we expect this increase to be offset by a reduction in D–SNP look-alikes due to our changes to the § 422.514(e) transition process, which will limit use of the § 422.514(e) transition process to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Under our provision, D–SNP look-alikes transitioning effective for plan year 2025 and plan year 2026—including the newly identified D–SNP look-alikes based on the threshold lowered to 70 percent and then 60 percent—can continue to use the existing transition process under § 422.514(e). Once the newly identified D–SNP look-alikes at the lower thresholds complete their transitions for plan year 2025 and plan year 2026, the § 422.514(e) transition process can only be used for D–SNP look-alike transitioning enrollees into D–SNPs. We believe this limit will give MA organizations a stronger incentive to avoid creating D–SNP look-alikes, due to the more limited opportunity for these plans to transition enrollees to non-D–SNPs. The limit on the § 422.514(e) transitions will be effective for plan year 2027 and subsequent years. We believe that these 12 D–SNP look-alikes will non-renew and transition their enrollment into a D–SNP or other MA–PD plan. The annual burden is summarized in Table J7.

As indicated, the following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

An individual transitioned from a D–SNP look-alike to another MA–PD plan may stay in the MA–PD plan receiving the enrollment or, using the AEP or another enrollment period (such as the MA OEP), make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA–PD plan or receiving services through Traditional Medicare and enrollment in a stand-alone PDP. Because the enrollment transition process is effective on January 1 and notices would be provided during the AEP, affected individuals have opportunities to make different plan selections through the AEP (prior to January 1) or the MA open enrollment period (OEP) (after January 1). Affected individuals may also qualify for a special enrollment period (SEP), such as the SEP for plan non-renewals at § 422.62(b)(1) or the SEP for dually eligible/LIS beneficiaries at § 423.38(c)(4), which we are revising as discussed in section VIII.F. of this final rule. Based on our experience with D–SNP look-alike transitions through plan year 2024, we estimate that 98 percent of the 53,334 D–SNP look-alike enrollees (52,267 enrollees = 53,334 enrollees × 0.98) in the 30 non-SNP MA plans with dually eligible enrollment of 70 to 79.9 percent and 98 percent of the 92,100 D–SNP look-alike enrollees (90,258 enrollees = 92,100 enrollees × 0.98) in the 40 non-SNP MA plans with dually eligible enrollment of 60 to 69.9 percent would transition into another plan under the same parent organization as the D–SNP look-alike. Of these 142,525 transitioning enrollees (52,267 enrollees + 90,258 enrollees), our experience with D–SNP look-alike transitions through plan year 2023 suggests that 14 percent will select a new plan or the Traditional Medicare and PDP option rather than accepting the transition into a different MA–PD plan or D–SNP under the same MA organization as the D–SNP in which they are currently enrolled. For plan year 2025, we estimate that 7,317 enrollees (52,2677 transitioning D–SNP look-alike enrollees * 0.14), will opt out of the new plan into which the D–SNP look-alike transitioned them. For plan year 2026, we estimate that 12,636 enrollees (90,258 transitioning D–SNP look-alike enrollees * 0.14), will opt out of the new plan into which the D–SNP look-alike transitioned them. Consistent with the per response time estimate that is currently approved by OMB under control number 0938–0753 (CMS–R–267), we continue to estimate that the enrollment process requires 20 minutes (0.3333 hr).

Based on the aforementioned discussion, Table J8, summarizes the hour and dollar burden for added enrollments for years 2025 to 2027.

TABLE J8: BURDEN ON ENROLLEES FOR YEARS 2025-2027

Year	Number of Affected Enrollees	Time /Enrollee (hr)	Total Time (hr)	Total Cost (@ $20.71/hr) ($)*
2025	7,317	0.3333	2,439	50,512
2026	12,636	0.3333	4,212	87,231
2027	3,421	0.3333	1,140	23,690
Total	23,374	0.9999	7,791	161,433
Average	7,791 (23,374/3)	0.3333 (0.9999/3)	2,597 (7,791/3)	53,811 (161,433/3)

*Had we used $29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from $53,811 to $77,326 an increase of $23,515.

As stated previously, we believe that in 2027 and subsequent years, 12 plans will be identified as D–SNP look-alikes and therefore this rule would have a much smaller impact on MA enrollees after the initial period of implementation. Since the current 70 non-SNP MA plans with dually eligible enrollment of 60.0 to 79.9 percent have 145,434 enrollees in 70 plans, we estimate 24,932 enrollees (145,434 enrollees * 12/70 plans) in 12 plans. For plan year 2027, we estimate that 98 percent of the 24,433 D–SNP look-alike enrollees (24,433 enrollees = 24,932 enrollees × 0.98) in the 12 non-SNP MA plans would transition into another plan under the same parent organization as the D–SNP look-alike. We further estimate that we estimate that 3,421 enrollees (24,433 transitioning D–SNP look-alike enrollees * 0.14) will opt out of the new plan into which the D–SNP look-alike transitioned them. The burden on D–SNP look-alike enrollees is summarized in Table J7. The average annual enrollee burden over 3 years is presented in Table J8.

We received no comments specific to our analysis of paperwork burden and, except for modifications made to reflect 2024 plan year experience with D–SNP look-alike transitions, we are therefore finalizing our estimates as is.

13. ICRs Regarding Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

The following changes will be submitted to OMB for approval under control number 0938–1421 (CMS–10802).

The multi-language insert (MLI) required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These were the 15 most common non-English languages in the United States when we reinstituted the MLI in the May 2022 final rule. Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the 5 percent threshold, where it determines that including the language would be appropriate.

As discussed in section III.P. of this final rule, we are finalizing an update to §§ 422.2267(e)(31) and 423.2267(e)(33) to require that notice of availability of language assistance services and auxiliary aids and services be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency in a State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. We are finalizing this provision with one amendment: We are adding ''or States associated with the plan's service area'' between the language ''relevant State'' and ''and must be provided . . .'' to reduce the burden on organizations with plan benefit packages that operate in more than one State and conform with the OCR proposed rule, and to clarify that the requirement is based on the plan benefit package service area. Thus, under the final provision, MA organizations and Part D sponsors would send the Notice of Availability in English and at least the 15 most common non-English languages in a State or States associated with the plan's service area instead of the current MLI in the 15 most common non-English languages nationally. This policy is consistent with a proposed rule that OCR published in August 2022 (87 FR 47824). We also expect that this policy will better align with the Medicaid translation requirements at § 438.10(d)(2).[260] We are modifying the language to note that this is a model communication material rather than a standardized communication material because we are no longer specifying the exact text that must be used. Even though the MA organizations and Part D sponsors could change the Notice of Availability, we are not accounting for such changes because we do not expect any MA organizations or Part D sponsors to make such changes. It is possible that some States may require the use of a specific tagline to meet this requirement, however if this is the case, we again do not anticipate an additional burden to plans since the State would provide the specific language and translations to be used.

We did not expect this policy to create any new collection of information burden for MA organizations or Part D sponsors since the August 2022 proposed rule indicates that OCR would provide translations of the Notice of Availability. Also, the MA organizations and Part D sponsors are already distributing the MLI and, under this final provision, would instead distribute the Notice of Availability, so we do not anticipate any new burden associated with printing or mailing. In addition, the Notice of Availability will be a one-page document that would never be sent

[260] We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our NPRM would not impose additional burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

alone and therefore does not create additional postage costs.

We expected some new burden for MA organizations and Part D sponsors operating plans across multiple States. Rather than sending the same MLI with the same 15 non-English language translations to plans in any State, under the final rule the plans under these MA organizations or Part D sponsors would need to send the Notice of Availability with translations in at least the 15 most common non-English languages in each State or States in which the plan operates. Based on plan year 2023 data, we estimated there are approximately 20 MA parent organizations offering MA plans in multiple States with approximately 3,900 PBPs and approximately 20 Part D sponsors offering Part D plans in multiple States with approximately 1,400 Part D plans. Since many of these parent organizations have MA organizations at the State level, we estimated that these 20 parent organizations have approximately 220 MA organizations covering PBPs by State. Similarly, we estimated that the 20 Part D sponsors had approximately 50 parent organizations covering PBPs by State. We believe the parent organizations will update systems software and plan policies and procedures as well as train staff at the MA organization and Part D sponsor level to cover all PBPs and Part D plans, respectively, offered in a State. We expected that MA organizations and Part D sponsors would need one software engineer working one hour to update systems software in the first year with no additional burden in future years and 1 hour at $127.82/hr to update systems software in the first year with no additional burden in future years and one business operations specialist working 1 hour at $79.50/hr to update plan policies and procedures and train staff in the first year with no additional burden in future years.

For MA organizations, we estimated the burden for plan year 2025 at 440 hours (220 MA organizations * 2 hr/plan) at a cost of $56,241 (440 hr * $127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State or States-specific languages is distributed with other communications and marketing materials. We estimated the burden for MA organizations for plan year 2025 to be 440 hours (220 MA organizations * 2 hr/plan) at a cost of $34,980 (440 hr * $79.50/hr) for a business operations specialist to update plan policies and procedures and train staff.

For Part D sponsors, we estimate the burden for plan year 2025 at 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of $12,782 (100 hr * $127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State or States-specific languages is distributed with other communications and marketing materials. We estimated the burden for Part D sponsors for plan year 2025 to be 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of $7,950 (100 hr * $79.50/hr) for a business operations specialist to update plan policies and procedures and train staff. We do not anticipate any new burden to plans after the initial year.

We also note that, as part of the current MLI required at §§ 422.2267(e)(31) and 423.2267(e)(33), MA organizations and Part D sponsors must already include additional languages that meet the 5 percent service area threshold as required under §§ 422.2267(a)(2) and 423.2267(a)(3). Thus, MA organizations and Part D sponsors must currently review the most frequently used languages in a service area beyond the top 15 national languages. As a result, we did not believe the burden will be greater than our estimate noted previously.

We do not believe that the modified policy poses any additional impact on burden. We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is.

14. ICRs Regarding Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d))

The following changes will be submitted to OMB for approval under control number 0938–1154 (CMS–10396). Based on comments summarized in section III.E., we are finalizing our proposed changes to the MTM eligibility criteria with modification, as follows:

- Requiring plan sponsors to target all core chronic diseases and continuing to allow them to Add other chronic diseases.
- Codifying the current nine core chronic diseases in regulation and adding HIV/AIDS, for a total of 10 core chronic diseases.
- Maintaining the maximum number of covered Part D drugs a sponsor may require at eight drugs, requiring sponsors to include all Part D maintenance drugs in their targeting criteria, and continuing to allow them to include all covered Part D drugs in their targeting criteria.
- Revising the annual cost threshold ($5,330 in 2024) methodology to be based on the average annual cost of eight generic drugs ($1,623 for 2025 based on 2023 data).

We are also revising our estimates to reflect our final policies and updated data, including more accurate postage rates. Taken together, we estimate that the changes to the MTM eligibility criteria will increase the number (and percentage) of Part D enrollees eligible for MTM services by 3,466,029 beneficiaries, from 3,599,356 (7 percent of all Part D enrollees) to 7,065,385 (13 percent of all Part D enrollees). While we considered multiple alternative proposals, we ultimately finalized this combination of changes as a way to close significant gaps in MTM eligibility while being responsive to concerns about program size and burden on Part D sponsors.

Under § 423.153(d)(1)(vii), all MTM enrollees must be offered a CMR at least annually and TMRs no less than quarterly. A CMR is an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth, that includes a review of the individual's medications and may result in the creation of a recommended medication action plan as required in § 423.153(d)(1)(vii)(B)(*1*) as amended in this final rule. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. For ongoing monitoring, sponsors are required to perform TMRs for all beneficiaries enrolled in the MTM program with follow-up interventions when necessary. The TMRs must occur at least quarterly beginning immediately upon enrollment in the MTM program and may address specific or potential medication-related problems. TMRs may be performed to assess medication use, to monitor whether any unresolved issues need attention, to determine if new drug therapy problems have arisen, or assess if the beneficiary has experienced a transition in care. Under § 423.153(d)(1)(vii)(E), plans are also 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 on plan sponsors to conduct CMRs (labor cost) and mail the written CMR summaries (non-labor cost) to the additional beneficiaries that will be targeted for MTM enrollment based on our revisions. We also estimate the cost of sending safe disposal information to the beneficiaries who will 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 do not Accept the offer of a CMR.

- *The burden for pharmacists to complete the additional CMRs:* Based on internal data, we found 66.2 percent of MTM program enrollees accepted the offer of a CMR in 2022. To estimate the cost of conducting the additional CMRs, we multiply the expected number of additional MTM program enrollees (3,466,029) by 0.662 to obtain the number of additional CMRs we estimate will actually be conducted (2,294,511). We estimate a pharmacist would take 40 minutes (0.6667 hr) at $124.44/hr to complete a CMR. Thus, the total burden is 1,529,750 hours (0.6667 hr/CMR * 2,294,511 enrollees who accept the CMR offer) at a cost of $190,362,090 (1,529,750 hr * $124.44/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 double-sided (including 1 page for information regarding safe disposal). The cost of mailing one CMR summary is the cost of postage plus the cost of printing one CMR summary. First-class postage costs $0.64 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). Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope. Therefore, the cost of printing the average CMR summary is $1.0220 ($0.64 postage for the first ounce + 0.24 for the second ounce + 7 sheets * $0.007 for paper + 7 sheets*$0.007 for toner + 0.044 for envelopes). And taken as a whole, the annual cost of mailing CMRs to the additional 2,294,511 beneficiaries expected to accept the CMR offer is $2,344,990 (2,294,511 enrollees × $1.0220/mailing).
- *Mailing costs for safe disposal information:* Out of the 3,466,029 additional beneficiaries expected to be targeted for MTM based on the revised criteria, we expect that 33.8 percent or 1,171,518 (3,466,029 * 0.338) beneficiaries will decline a CMR. These beneficiaries 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 standalone 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. If the letter does not contain private health information and thus bulk mailing costs (which include the envelope, typically a fold over paper) is used, the cost to mail one page of safe disposal information is $0.01495 per enrollee [(1 page $0.007/sheet) + (1 page * $0.007 toner) + ($0.19/200 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 $17,514 ($0.01495 * 1,171,518).

Therefore, the total burden associated with the finalized revisions to the MTM targeting criteria is 1,529,750 hours and $192,724,594 ($190,362,090 for a pharmacist to perform the CMRs for beneficiaries newly targeted for MTM under the revised criteria + $2,344,990 to mail the CMR written summary in the CMS Standardized Format with safe disposal information + $17,514 for mailing information regarding safe disposal to beneficiaries newly targeted for MTM who do not receive a CMR).

We received the following comments on the estimates included in this section of the proposed rule, and our responses follow:

Comment: A commenter pointed out that the increase in program size and burden would not be evenly distributed, and that some plans would be disproportionately affected due to member population and plan type. Another commenter suggested simplifying the program by focusing only on CMRs to improve participation and decrease the cost.

Response: We acknowledge that eligibility rates for MTM are not evenly distributed among Part D contracts. Similar to current MTM programs, some contracts may have actual MTM enrollment rates above or below the average rate for the program as a whole. CMS took the cost burden into consideration when developing its policies for this final rule and modified the eligibility criteria to lessen the burden on plans but still provide access to MTM to more beneficiaries. As a key component of the MTM program, the CMR is also the costliest component as evidenced by our calculations. Therefore, it is unlikely that focusing solely on the CMR would significantly decrease the cost burden.

Comment: One commenter suggested that the time for a pharmacist or other qualified provider to complete the CMR was underestimated and should be 60 minutes. While the average CMR consultation with the enrollee may take 20–40 minutes, the pharmacist or other qualified provider spends additional time reviewing the case before the consultation with the enrollee and preparing the CMR summary.

Response: CMS disagrees. The time spent conducting a CMR for the purposes of our burden calculations is an average; as supported by the range of 20 to 60 minutes provided in this comment, 40 minutes is an accurate estimate. CMS considers the preparatory time for the CMR summary to be negligible since most sponsors and MTM providers use an automated system to complete the Standardized Format.

15. ICRs Regarding Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

The following changes will be submitted to OMB for approval 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; therefore, no additional burden is anticipated from this change. 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 codifying current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations will 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 will 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 0.117 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 $512,775 (6,450 hr * $79.50/hr)

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

16. ICRs Regarding Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement 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 approval 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 $7.95 (0.1 hr × $79.50/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 $954 (12 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

17. ICRs Regarding Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

The following changes will be submitted to OMB for approval 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 change will not add to existing reinstatement processes; therefore, no additional burden is anticipated. However, because a burden estimate for these enrollment reinstatement notifications has not previously been submitted to OMB, we are correcting that oversight by requesting OMB's review and approval under the aforementioned control number.

We are codifying 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 will 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 will 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 will take 1 minute (0.017 hr) at $79.50/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 $305,280 (3,840 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

18. 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).

In this rule, §§ 422.528, 422.529, 423.521, and 423.522 will permit 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. In the December 2022 proposed rule, we had erroneously estimated the burden of the proposed provision. We are correcting that oversight in this final rule by removing such burden since the preparation and submission of appeals are in response to an administrative action, investigation or audit pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). In this regard, the preparation and submission of appeals

are not subject to the requirements of the PRA.

19. ICRs Regarding Personnel Requirements Under PACE (§§ 460.64 and 460.71)

The following changes will be submitted to OMB for approval 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 IX.C. of this final rule, we are finalizing our proposal 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 $74.02/hr for a compliance officer at each PACE organization to update these materials. In aggregate, we estimate a one-time burden of 156 hours (156 PACE organizations * 1 hr) at a cost of $11,547 (156 hr * $74.02/hr) for the update of policies and procedures.

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 $74.02/hr and 1 hour of work by the PCP at $229.52/hr. The weighted hourly wage for the compliance officer and PCP to create a risk assessment tool is $105.12/hr ([(4 hr * $74.02/hr) + (1 hr * $229.52/hr)]/5 hr of aggregate burden). In aggregate, we estimate a one-time burden of 780 hours (156 PACE organizations * 5 hr) at a cost of $81,994 (780 hr * $105.12/hr) for both the compliance officer and PCP roles in developing the risk assessment tool.

Based on internal CMS data, there were 156 active PACE organizations as of February 2024. This number of active PACE organization represents an increase of 7 PACE organizations from the 149 active PACE organizations counted in the December 2022 proposed rule and based on September 2022 data.

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

20. ICRs Regarding Service Delivery Under PACE (§ 460.98)

The following changes will be submitted to OMB for approval 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 final rule, but as discussed in section IX.D. of this final rule, we are finalizing our proposal to add required maximum 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 finalized 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 $74.02/hr to update the necessary materials. Therefore, we estimate a one-time burden of 156 hours (156 PACE organizations * 1 hr) at a cost of $11,547 (156 hr * $74.02/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

21. ICRs Regarding PACE Participant Rights (§ 460.112)

The following changes will be submitted to OMB for approval 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 IX.G. of this final rule, we are finalizing our proposal to add new participant rights and modify existing participant rights to enhance participant protections. Specifically, we are finalizing our proposal 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. Under our finalized changes to § 460.112, PACE organizations must 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 $74.02/hr to update these materials.

Additionally, PACE organizations must 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 $74.02/hr.

In aggregate, we estimate a one-time burden of 624 hours (156 PACE organizations * (2 hr + 2 hr)) at a cost of $46,188 (624 hr * $74.02/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. As discussed in section IX.G. of this final rule, we are finalizing the requirement that PACE organizations provide participants with written documentation explaining the different treatment options including palliative, comfort, and end-of-life care services. Specifically, we are finalizing the requirement that PACE organizations must 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 $85.60/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 $60.34/hr.

For tailoring information within the written templates and providing written materials to participants as specified at finalized § 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 $95.66/hr [(1 hr * $85.60/hr (RN)) + (0.1667 hr * $60.34/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 $81.99/hr (total cost of $95.66/1.1667 hr).

Using these assumptions, we estimate the ongoing burden for the finalized requirements at § 460.112(c)(5) would affect 12,169 participants (60,847 enrollees times 20 percent of participants who are expected to need end-of-life explanations). Therefore, to tailor and mail materials there is an annual burden of 14,198 hours (12,169 affected participants * 1.1667 hr) at a cost of $1,164,094 (14,198 hr * $81.99/hr).

We are also finalizing our proposal requiring that PACE organizations 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 $60.34/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. Based on CMS internal data, the total national enrollment in PACE as of February 2024 was 60,847. This enrollment data represents an 11 percent increase from the national PACE enrollment data utilized in the December 2022 proposed rule, 54,637 enrollees, which was based on September 2022 enrollment data.

We estimate an ongoing burden for PACE organizations' MSW to explain treatment options to participants as specified at § 460.112(e)(2) to be 12,169 hours (60,847 participants * 0.20 * 1 hr) at a cost of $734,277 (12,169 hr to discuss treatment options * $60.34/hr).

We estimate a total one-time burden of 624 hours at a cost of $46,188 and a total annual ongoing burden of 26,367 hours (14,198 hr + 12,169 hr) at a cost of $1,898,371 ($1,164,094 + $734,277).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations, national PACE enrollment data, and changes to mean hourly wages.

22. ICRs Regarding PACE Grievance Process (§ 460.120)

The following changes will be submitted to OMB for approval 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 IX.H. of this final rule, PACE organizations are already required to develop procedures on processing grievances and to provide notification of the grievance process to participants upon enrollment and at least annually. We are finalizing our proposed changes to further require that PACE organizations update those procedures. Specifically, we are finalizing our proposal that written or oral notification of the grievance resolution must include a summary of the grievance issues, a summary of the findings for each distinct issue that requires an investigation, 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 (if applicable). Our finalized changes, which add requirements on what must be included in grievance resolution notifications, require PACE organizations 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 finalized changes to § 460.120 will impact the annual hours of burden for PACE organizations, because they are already required to 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 requirement.

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 $74.02/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 $74.02/hr. For the written grievance resolution notification, we estimate it will take the compliance officer 1 hour to revise the written resolution notification at $74.02/hr.

In aggregate, we estimate it would take PACE organizations 624 hours [156 PACE organizations * (2 hr + 1 hr + 1 hr)] at a cost of $46,188 (624 hr * $74.02/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

23. ICRs Regarding PACE Participant Notification Requirement for PACE Organizations With Past Performance Issues or Compliance Deficiencies (§ 460.198)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

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, this rule adds a new provision, § 460.198, which gives 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 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 will 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 at $74.02/hr to complete and send out the template (which would be automated). In aggregate, we estimate it would take 2 hours (2 PACE organizations * 1 hr) at a cost of $148 (2 hr * $74.02/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

24. ICRs Regarding Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs) (§§ 422.2274(g) and 423.2274(g))

The following changes will be submitted to OMB for approval under control number (0938–0753) (CMS–R–267).

As explained in section VI.A. of this rule, personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another when prior express written consent is given by the beneficiary. Additionally, we codified that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each TPMO receiving the data and allows the beneficiary to consent or reject to the sharing of their information with each entity. We expect that each TPMO that collects personal beneficiary data and intends to share it with TPMOs must update their disclosure process to obtain individual consent for each TPMO with whom it will share the information. We expect that this collection of a consent to have information shared with other TPMOs will impact both TPMOs and Medicare beneficiaries.

a. Beneficiaries

To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries enrolling through agents and brokers that received their contact information from a TPMO and the time it takes for the beneficiary to complete the consent to sharing their information with specific entities. First, we estimate that it will take a beneficiary approximately five minutes to read the disclosure and provide consent to have their information shared with the entities of their choosing. We estimate that there are approximately 2 million new MA enrollees every year [261] and approximately 50 percent of those enrollees utilized a TPMO and/or agent/broker to assist with their enrollment into an MA plan.[262] Thus, in total, we expect that 1,000,000 (2,000,000 new MA enrollees * 50 percent assisted by an agent broker) beneficiaries to spend five minutes (0.083 hr) consenting or rejecting to the disclosure resulting in an aggregate burden of 83,000 hours (1 million new enrollees * 0.083 hr) and $1,718,930 (83,000 hr * $20.71/hr).

b. TPMOs

To estimate the information collection burden on TPMOs, we have estimated the number of TPMOs that collect personal beneficiary data for purposes of marketing or enrolling them into an MA or Part D plan. The most current industry profile for Market Research and Analysis and Marketing Specialists provided by the U.S. Bureau of Labor Statistics [263] states that there are 66,900 people employed in management capacity in this area. We estimate that there are approximately 10 managers per company,[264] resulting in 6,690 marketing organizations (66,900 people in management capacity divided by 10 managers per organization). Further, we estimate that 10 percent of these companies are operating in the healthcare industry,[265] which results in about 669 TPMOs or other entities (6,690 organizations * 0.10) that potentially would need to comply with this rule. We estimate it will take approximately 20 hours for a single TPMO manager and a single web and software developer to update the proper disclosure and form to obtain consent and a software engineer to program it into the company's workflow and process for collection. We therefore use the average wage of $136.17/hr (the average of $152.20/hr for a marketing manager and $120.14/hr for a software and web developer) In aggregate we estimate a burden of 13,380 (669 entities * 20 hr) at a cost of $1,821,955 (13,380 hr * $136.17/hr).

25. 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 VII. of this final rule, we are finalizing adding, removing, and updating certain measures. Most of the new measures will be calculated from administrative data and, as such, there will be no increase in plan burden. The other measure-level changes entail moving existing measures from the display page to Star Ratings, which also will have no impact on plan burden. We are also finalizing a series of technical clarifications related to QBP appeals processes, consolidations, and weighting of measures with a substantive specification change. The finalized 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),

[261] Published CMS data (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata*) shows MA non employer enrollment increasing steadily by 2 million a year since 2020. It shows PDP enrollment decreasing steadily by ½ million a year. This number is an overestimate since it includes deaths, ignores migrations from MA to FFS, ignores the downward trend in PDPs, and ignores migrations between plans.

[262] This was stated in the NPRM. Additionally the following source supports this: *https://deftresearch.com/wp-content/uploads/2023/11/Deft-Research-Gut-Check-Study-Snapshot.pdf.*

[263] *https://www.bls.gov/oes/current/oes131161.htm* Another BLS page for the profile specific to ''Marketing Managers'', *https://www.bls.gov/oes/current/oes112021.htm,* lists 44710 managers. In our estimates we used the higher estimate for the number of managers (66,900) and higher estimate for the mean hourly wage ($76.10, for Marketing Managers, Occupational code 11–2021) We then adjusted this for overtime and fringe and benefits.

[264] Typically, managers include top-level, middle-level, first-line, and team-leads. Top level itself might include the president, vice-president, CEO, and CFO. Thus, we believe the number 10 reasonable and possibly an underestimate.

[265] The BLS does not further break down the area specialty, ''Market Research Analysts and Marketing Specialists'' Occupational code 13–1161, by sub-areas. However, the area includes marketing for real-estate, life and property insurance, scientific and technical companies, and software companies. Thus, we believe 10 percent a reasonable estimate for health-insurance marketing specialists.

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 making changes under any of the aforementioned control numbers.

C. Summary of Information Collection Requirements and Associated Burden Estimates

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TABLE J9: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§ 422.116(b)(2) and (d)(2) and (5)	Network Adequacy for Behavioral Health	0938-1346 (CMS-10636)	742 Plan Sponsors	742	0.0833	62	79.50	4,929	-
§§ 423.4, 423.100, 423.104, 423.120, and 423.128	Changes to an Approved Formulary Submission	0938-0964 (CMS-10141)	197 Plan sponsors	68,232	Varies	(20,952)	Varies	(955,616)	(955,616)
§§ 423.100 and 423.153	DMP:Case Management	0938-TBD (CMS-10874)	319 Plan Sponsors	30,365	5	(27030)	111.16	(3,004,655)	(3,004,655)
§§ 423.100 and 423.153	DMP:Enrollee notification	0938-TBD (CMS-10874)	319 Plan Sponsors	1,518	0.1667	(1066)	38.70	(41,254)	(41,254)
§§ 423.100 and 423.153	DMP: CMS Notification	0938-TBD (CMS-10874)	319 Plan Sponsors	30,365	0.0167	(90)	38.70	(3,483)	(3,483)
§ 422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI: Reasonable expectation of improving health	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	2	1548	98.84	153,004	-
§ 422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI: Reasonable expectation of improving health	0938-0753 (CMS-R-267)	310 MA Plans Offering SSBCI	10,000	8	80000	85.60	6,848,000	6,848,000
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	4	3096	127.82	395,731	-
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	1	774	79.50	61,533	-
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	32,000,000	Non Labor	Non Labor	Non Labor	23,232,000	23,232,000
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	0.5	483	74.02	35,752	-
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	8	7728	120.14	928,442	-
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	0.1667	161	79.50	12,800	12,800
§ 422.116(b) through (e)	Exceptions for Network Adequacy	0938-1346 (CMS-10636)	10 MA Plans	10	0.0833	0.8	79.50	64	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment: Notification, Software updates	0938-0753 (CMS-R-267)	50 Plans	50	8	400	127.82	51,128	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment:Integrated SEP, Software	0938-0964 (CMS-10141)	113 SNPS	113	4	452	127.82	57,775	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment: Notification, Update Policies	0938-0753 (CMS-R-267)	50 Plans	50	4	200	79.50	15,900	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment:Integrated SEP, Update Policies	0938-0964 (CMS-10141)	113 SNPS	113	4	452	79.50	35,934	-
§ 422.514(d) and (e)	D-SNP Look alikes	0938-0753 (CMS-R-267)	25 MA Plans	25	2	50	79.50	3,975	3,975

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§ 422.514(d) and (e)	D-SNP Look alikes	0938-0753 (CMS-R-267)	7791 Enrollees	7,791	0.3333	2597	20.71	53,811	53,811
§§ 422.2267 and 423.2267	Multi Language Insert: Software, Part C	0938-1421 (CMS-10802)	220 Plans	220	2	440	127.82	56,241	-
§§ 422.2267 and 423.2267	Multi Language Insert: Updates, Part C	0938-1421 (CMS-10802)	220 Plans	220	2	440	79.50	34,980	-
§§ 422.2267 and 423.2267	Multi Language Insert: Software, Part D	0938-1421 (CMS-10802)	50 States	50	2	100	127.82	12,782	-
§§ 422.2267 and 423.2267	Multi Language Insert: Update Policies, Part D	0938-1421 (CMS-10802)	50 States	50	2	100	79.50	7,950	-
(§ 423.153(d))	MTM: CMRs	0938-1154 (CMS-10396)	3,466,029 Enrollees	2,294,511	0.6667	1529750	124.44	190,362,090	190,362,090
(§ 423.153(d))	MTM: Mail CMRs	0938-1154 (CMS-10396)	3,466,029 Enrollees	2,294,511	NA	NA	NA	2,344,990	2,344,990
(§ 423.153(d))	MTM: Mail Safe Disposal	0938-1154 (CMS-10396)	3,466,029 Enrollees	1,171,518	NA	NA	NA	17,514	17,514
§ 422.74	Notice for Involuntary Disenrollment from SNPS	0938-0753 (CMS-R-267)	620 Special Needs Plans	55,127	0.117	6450	79.50	512,775	512,775
§ 422.74(b)(2)	Involuntary Disenrollment from MSAs	0938-0753 (CMS-R-267)	4 MSA Plans	124	0.1	12	79.50	954	954
§§ 422.60 and 423.32	Reinstatements from Cancellation of New Enrollments	0938-1378 (CMS-10718)	803 (740 MA Organizations and 63 Part D Sponsors)	225,906	0.017	3840	79.50	305,280	305,280
§§ 460.64 and 460.71	PACE Personnel Requirements: Update Policies and Procedures	0938-0790 (CMS-R-244)	156 PO	156	1	156	74.02	11,547	-
§§ 460.64 and 460.71	PACE Personnel Requirements: Risk Assessment Tool	0938-0790 (CMS-R-244)	156 PO	156	5	780	105.12	81,994	-
§ 460.98	PACE Service Delivery	0938-0790 (CMS-R-244)	156 PO	156	1	156	74.02	11,547	-
§ 460.112	PACE Participant Rights: Update materials & create templates	0938-0790 (CMS-R-244)	156 PO	156	4	624	74.02	46,188	-
§ 460.112	PACE Participant Rights: Taylor Templates for individual enrollees	0938-0790 (CMS-R-244)	156 PO	12,169	1.1667	14198	81.99	1,164,094	1,164,094
§ 460.112	PACE Participant Rights: Explain options and answer questions	0938-0790 (CMS-R-244)	156 PO	12,169	1	12169	60.34	734,277	734,277
(§ 460.120	PACE Grievance Process: Update policies, annual notifications, and resolution notifications	0938-0790 (CMS-R-244)	156 PO	156	4	624	74.02	46,188	-
§ 460.198	PACE participant notification of past performance issues	0938-0790 (CMS-R-244)	2 PO	2	1	2	74.02	148	148
§§ 422.2274(g) and 423.2274(g)	TMPO Sharing of Information	0938-0753 (CMS-R-267)	-	1,000,000	0.083	83000	20.71	1,718,930	1,718,930

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§§ 422.2274(g) and 423.2274(g)	TMPO Sharing of Information	0938-0753 (CMS-R-267)	669 MA Plans	669	20	13380	136.17	1,821,955	1,821,955
Totals			3474836	39,222,620	*Varies*	1,715,087	*Varies*	227,178,194	225,128,585

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XI. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Program of All-Inclusive Care for the Elderly (PACE). This final rule includes several new policies that would improve these programs beginning with contract year 2025 as well as codify existing Part C and Part D sub-regulatory guidance. This final rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process and the appeal process for quality bonus payment determination that would take effect 60 days after publication. Revisions to existing regulations for the use and release of risk adjustment data would also take effect 60 days after publication of a final rule. Additionally, this final rule would implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- Consolidated Appropriations Act (CAA) of 2023

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and 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). The Executive Order 14094, entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.), amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 $200 million or more in any 1 year, or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under 3(f)(1). The total economic impact for this final rule exceeds $200 million in several years. Therefore, based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule meets the criteria set forth in 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 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 2023, the most recent year for which we have complete data, that threshold is approximately $183 million. This final rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $183 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this final 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.

We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

C. Cost of Reviewing the Rule

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that—

- The hourly cost per reviewer for reviewing this final rule is $123.06 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Had a general business operations specialist been used (say for an entity without medical and health service managers) the cost per hour would be less than that for a medical and health services manager. Therefore, we are at most over-estimating the cost per hour and will use $123.06/hr.
- We estimate that there will be less than 2,000 reviewers of this final rule: There are currently less than 1,000 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, PBMs). We expect that each organization will designate one person to review the rule. Therefore, a reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.
- The rule is about 150,000 words. Average reading speeds vary from 180 to 240 words per minute. Since the rule is technical and presumably notes are being taken, we use the lower estimate. Furthermore, since in addition to notetaking, summaries would be submitted to leadership we are lowering the 180 words/minutes to 150. Accordingly, we assume it would take staff 17 hours to review this final rule (150,000 words/150 words per minute/60 minutes hour). This may be an overestimate since each entity will likely only read the provisions affecting them and not the entire rule.
- Therefore, the estimated cost per reviewing entity for reading this entire rule is $2,100 (17 hr × $123.06/hr), and the total cost over all entities for reviewing this entire final rule is $ 4.2 million ($2,100 × 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. Thus, it is very likely that on average only half or a

quarter of the rule will be read resulting in a range of $2 million to $5 million.

Please 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 local, or region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

D. 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 finalized in this rule. These policies codify, modify, and update current guidance governing MA organization and Part D Plan Sponsor 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; (3) agents and brokers, and (4) enrollees. Some descriptive data on these stakeholders are provided in Table K–1.

TABLE K-1: STAKEHOLDERS AFFECTED BY THIS RULE, THEIR NAICS CODE, AND THRESHOLD FOR SMALL BUSINESS STATUS

Stakeholder	NAICS Code (2022)	Threshold for Small Business (2021) (in millions of dollars)
Pharmacy and Drug stores	456110	37.5
Direct Health and Medical Insurance Carriers	524114	47
Ambulatory Health Services	621	
Dialysis Centers	621492	47
Insurance Brokerages & Agencies	524210	15
Physician offices	621111	16
Hospitals	622	47
Skilled Nursing Facilities	623110	34

We are certifying that this final rule 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 final rule).

MA plans can also offer extra benefits, that is, benefits not covered under Traditional Medicare Parts A and B, called supplemental benefits. These benefits are paid for through enrollee premiums, rebate dollars or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Parts 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 Traditional Medicare, including lower cost sharing) 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.

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 the premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by MA and Part D plans is funded by a variety of government fundingsources and 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 and Part D regulations, such as those in this final 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 Traditional Medicare data; or (2)

the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

Therefore, 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:

- Pharmacies and Drug Stores, NAICS 446110;
- 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;
- Insurance Brokerages & Agencies, NAICS 524210;
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and
- SNFs, NAICS 623110.

Except for insurance brokers and agencies, each of these are providers that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs and PFFS MA plans, 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 that furnishes covered services to an MA enrollee accept payment that is at least what the provider would have been paid had the services been furnished to A Medicare FFS beneficiary.
- 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 health care provider or to use a particular price structure for payment by section 1854(a)(6)(B)(iii) of the Act.

Consequently, for providers, there is no additional cost burden above the already existing burden in Traditional Medicare.

Our finalized provision requires TPMOs that collect personal beneficiary data for purposes of marketing or enrolling them into an MA or Part D plan to obtain prior express written consent through a disclosure to share that data with another TPMO. In response to our proposal to ban the distribution of beneficiary data, one commenter said that CMS failed to provide a cost-benefit analysis showing the impact of a data distribution ban on TPMOs and independent agents. However, since we are not completely prohibiting the sharing of beneficiary data in this final rule, we expect that TPMOs can make adjustments to their disclosures to conform to these new requirements without a major disruption to their business model or having a negative impact on independent agents and brokers. Further, we believe beneficiaries that are interested in obtaining more information about their plan options will complete the required consent processes. We expect some minor reduction in collection of data and a corresponding reduction in the sharing of that data, to which beneficiaries did not previously consent, as this data sharing may not have been wanted by beneficiaries who unknowingly consented to the sharing, and which resulted in complaints received by CMS. This consent requirement and a reduction in unwanted contacts is, in fact, the goal of the provision. We, however, have no way of estimating how much data-sharing occurred nor do we know the extent to which requiring beneficiaries to consent to their data being shared will reduce the amount of data shared in the future.

Based on the previous discussion, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

There are certain indirect consequences of these provisions which also create impact. We have already explained that at least 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a 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 beneficiary rebate, which must be used to provide supplemental and/or lower beneficiary Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans.

If the provisions of this final rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, and/or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of proposed and final rules, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

Comment: As indicated above, one commenter commented that CMS did not provide a cost-benefit analysis of the impact of its provisions on TPMOs. Additionally, this commenter pointed out that completely banning sharing personal beneficiary data, as originally proposed in the NPRM, would have an adverse effect on small businesses.

Response: We agree that a prohibition on sharing personal beneficiary data without any exception would adversely affect TPMOs and small businesses alike. We are therefore modifying our original proposal by allowing the sharing of personal beneficiary data when it's specifically consented to by the beneficiary. The paperwork burden for this has been properly estimated in the Collection of Information section. Since we are not completely prohibiting the sharing of beneficiary data in this final rule, we expect that TPMOs can make adjustments to their disclosures to conform to these new requirements without a major disruption to their business model or having a negative impact or TPMOs. Further, we believe enrollees that are interested in obtaining more information about their plan options will complete the required consent process or forms. We expect some minor changes in collection corresponding to a reduction in the sharing of data, to which there previously was not a requirement for consent, and this data sharing and subsequent contact was previously not

wanted or desired or knowingly agreed to and resulted in complaints to CMS and others. The goal of the provision is to require the consent of beneficiaries to the sharing of their personal data. However, we have not provided a more detailed quantification of the effect of this consent requirement, since CMS lacks internal and external data for estimating how much unauthorized data sharing was occurring previously nor do we know the extent to which requiring a beneficiary to consent to their data being shared will reduce the amount of data sharing in the future.

Comment: Several commentators provided comments on the agent-broker compensation provision. They noted: (1) the lack of any cost analysis; (2) the possible adverse impact this would have on independent agent-brokers or small agencies; (3) the high volatility and variance of several line-items contributing administrative costs and expenses to agent broker compensation may be inconsistent with a uniform flat compensation rate, and iv) that not all line-item costs are mentioned in the NPRM. These comments came from both those who receive agent broker compensation as well as those (such as plans) who pay for them. The comments were both qualitative and quantitative. In particular, several commentators said that administrative costs were significantly higher than what we said in the NPRM; these quantitative estimates ranged from $50 to $500 per enrollee with many commentors targeting the higher amounts.

Response: Our finalized provisions simultaneously eliminate administrative payments but provide for higher compensation per enrollee. The increased compensation above the base line compensation rate is $100 for each new MA or PDP enrollee. As discussed in section X.X of the preamble and section X.C.10 of the collection of information section, our goals were to: (1) provide sufficient funding which would compensate agents, brokers, and related entities for their work; (2) not to give excesses; and (3) to select increases consistent with current payments (that is not exceeding current administrative payments). In other words, the finalized provision transfers funds currently being allocated to administrative to compensation in a transparent and uniform manner. We have consequently scored this impact as having no cost, and therefore do not believe this will have an adverse effect, either on TMPOs, FMOs, or independent brokers.

E. Anticipated Effects

Many provisions of this final rule have negligible impact either because they are technical provisions, clarifications, or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified. Throughout the preamble, we have noted when we estimated that provisions have no impact either because they are codifying already existing practices, or, for example, because contractors for CMS have asserted that changes work within their current contract without the need for additional compensation. Additionally, this Regulatory Impact Statement discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions' effects are estimated in section XXX of this final rule and in this RIA. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Statement cross-references impacts from section XXX of this final rule in order to arrive at total impact.

1. Effects of Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

We discussed in section III.Q. of this final rule two provisions to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS's ability to use and disclose MA encounter data for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. This final rule improves access to MA data by—

- Adding ''and Medicaid programs'' to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii); and
- Adding a new § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to State Medicaid agencies for the purpose of coordinating care for dually eligible individuals.

Together, these provisions clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). These proposals do not change the external entities allowed to request MA encounter data from CMS.

As discussed in sections X and III.Q. of this final rule, these provisions will allow external entities to voluntarily request MA encounter data for allowable data uses to support the Medicare program, Medicaid program, and Medicare and Medicaid combined purposes. In the November 2023 proposed rule, we noted that there was one area where this provision could have impacted the burden to CMS: CMS reviewing and fulfilling new MA encounter data requests. However, in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program final rule, when we initially established CMS disclosure of MA encounter data, we explained that we had determined that ''there are not any economically significant effects of the proposed provisions'' (79 FR 50445). The same applies for the proposed refinements to the approved data uses and the data disclosure in this rule. We received no comments specific to our analysis of burden. We are finalizing our estimate as-is.

2. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

We discussed collection of information burden associated with this provision in section X of this final rule. In this section, we describe the impacts of our changes to the dual/LIS SEP, new integrated care SEP, and contract limitations for non-integrated MA–PD plans.

These final provisions will impact dually eligible and other LIS eligible individuals that currently use the quarterly dual/LIS SEP to change their enrollment in MA–PD plans. We are finalizing a change the quarterly dual/LIS SEP to a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP. The finalized provision will allow individuals to switch PDPs or leave their MA–PD plans for Traditional Medicare (with a standalone PDP) in any month. The finalized dual/LIS SEP will no longer permit enrollment into MA–PD plans or changes between MA–PD plans (although such options would remain available through other enrollment periods and SEPs). In

addition, we are finalizing with modification a new integrated care SEP that will allow enrollment in any month into a FIDE SNP, HIDE SNP, or AIP to facilitate aligned enrollment as defined at § 422.2 for full-benefit dual eligible individuals who meet the qualifications of such plans.

We are finalizing §§ 422.504(a)(20) and 422.514(h) largely as proposed with modifications to § 422.514(h). These provisions will establish a new requirement for an MA organization, that, beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service area, that the MA organization's D–SNP(s) must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D–SNP's aligned Medicaid MCO. We are finalizing the proposed regulation at § 422.514(h) with a minor technical modification at § 422.514(h)(1) to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposal at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with minor technical modifications at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accept new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). Additionally, an MA organization (or its parent organization or another MA organization with the same parent organization) in this situation would only be able to offer one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO (with limited exceptions as described in section VIII.F. of this final rule). Further, beginning in plan year 2030, such D–SNPs must only enroll (or continue to cover) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO.

Full-benefit dual eligible individuals enrolled in a D–SNP that consolidates due to our proposals at §§ 422.504(a)(20) and 422.514(h) will be moved into a new plan. The impacted enrollees will receive materials about the plan consolidation and materials associated with the new plan. We believe the plan benefit packages of the plans required to consolidate to be similar if not the same and do not expect impact to enrollees.

We expect there to be an enrollment shift from MA–PDs into FIDE SNPs, HIDE SNPs, or AIPs over time as more D–SNPs align with Medicaid MCOs. Starting in plan year 2027, we expect new D–SNP enrollment to be limited and then we expect integrated D–SNP enrollment to accelerate in 2030 when D–SNPs under a parent organization with an affiliated Medicaid MCO would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated MCO.

We examined contract year 2023 bid data for D–SNPs that enroll beneficiaries in States that also use Medicaid managed care to cover some or all benefits for dually eligible individuals. In general, the data shows that the more integrated D–SNPs have higher per capita MA rebates than those in less integrated plans. MA rebates are used to reduce beneficiary cost sharing, lower beneficiary premiums, and provide additional supplemental benefits. MA rebates are calculated by multiplying the difference in the risk-adjusted benchmarks and the risk-adjusted bids by a percentage called the rebate percentage. The Federal Government retains the complement of the rebate percentage (or 1 − rebate percentage) multiplied by the difference in the risk-adjusted benchmarks and bids. The (risk-adjusted) bid-to-benchmark ratios, in general, are smaller for the more integrated plans versus the less integrated plans. This suggests that the more integrated D–SNPs can provide Traditional Medicare benefits (represented by the risk adjusted bid) at a lower or more efficient level than the less integrated D–SNPs. We have assumed that this provision's requirement for greater alignment between the D–SNP and the affiliated Medicaid MCO will lead to greater health benefit efficiencies and incur Federal Government savings since the Federal Government retains the complement of the difference between the submitted risk adjusted bids and benchmarks.

In calculating our estimates, we assumed savings would begin in 2027 when new D–SNPs enrollment would be limited. We expect integrated D–SNP enrollment and related savings to accelerate in 2030 when D–SNPs under a parent organization participating in Medicaid managed care would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated Medicaid MCO under the same parent organization. We estimated that the other elements of this proposal (including the proposed changes to the SEP) would have a negligible impact.

To develop the savings projections, we calculated the bid-to-benchmark ratios for the integrated D–SNPs based on the calendar year 2023 plan data and applied them to the coordination-only D–SNPs that we assume would convert to aligned D–SNPs by 2030. We assumed that a large percentage of the coordination-only D–SNP enrollment would convert to integrated D–SNPs by 2030. For trending purposes, we used 2023 bid data and 2023 enrollment data as the starting point and trended those data points by values found in the 2023 Medicare Trustees Report. We calculated gross costs (savings are represented by negative dollar amounts) by multiplying the per member per month expenditure differences by the enrollment that is projected to switch to aligned plans. Then, we calculated the net cost by multiplying the gross costs by the net of Part B premium amount which averages between 85.1 percent and 84.6 percent from 2025–2034. This yields an overall annual estimate of net Part C costs ranging from − $6 million in contract year 2027 to − $207 million in contract year 2034.

TABLE K-2: ESTIMATED PART C COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALLY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REBATE PMPM Difference	-	-	(13.10)	(13.16)	(13.02)	(12.89)	(12.93)	(13.04)	(13.92)	(14.51)	
PROJECTED CO D-SNP Enrollment Switchers to Aligned Medicare and Medicaid MCOs	-	-	41,578	81,567	119,630	1,303,863	1,334,476	1,361,197	1,385,109	1,405,696	
Gross Cost ($ millions):	-	-	(7)	(13)	(19)	(202)	(207)	(213)	(231)	(245)	(1,136)
Net of Part B Premium:	85.1%	85.0%	84.9%	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	
Net Cost ($ millions):	-	-	(6)	(11)	(16)	(171)	(175)	(180)	(196)	(207)	(961)

We performed a similar comparison of contract year 2023 bids for Part D on the same MA plans and their associated population. The data also suggests that the more integrated D–SNPs had lower combined bid and reinsurance amounts for contract year 2023. As a result, we also projected that there would be efficiencies when D–SNPs aligned more with the Medicaid MCOs. The observed 2023 difference (efficiency) in the combined bid and reinsurance amounts is projected with the corresponding D–SNP trend assumed in the 2023 Medicare Trustees' Report (not shown in that report). The Part D gross savings are the product of the efficiency and the associated switchers from Table K–3. Since the premiums for the Medicaid beneficiaries are subsidized, there would be no premium offset. As a result, the net savings would be the same as the gross savings. We estimated the net costs would range from −$7 million in contract year 2027 to −$286 million in contract year 2034.

We also have reviewed the impact to the Medicaid program and have concluded that the Medicaid impacts would be negligible. The majority of States have a ''lesser-of'' policy, under which the State caps its payment of Medicare cost sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. Under this policy, the Medicare payment and the cost sharing are not expected to increase resulting in non-significant impacts to Medicaid payments. For Part D, given that the Medicaid liability is limited to the beneficiary cost sharing and that the vast majority of dually eligible individuals qualify for low-income cost sharing, we anticipate no significant impacts to Medicaid costs.

TABLE K-3: ESTIMATED PART D COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALLY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REINSURANCE PMPM Difference	-	-	(14.09)	(14.25)	(14.67)	(15.00)	(15.30)	(15.87)	(16.47)	(16.97)	
Gross Cost ($ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)
Net Part D Premium:	0	0	0	0	0	0	0	0	0	0	0
Net Cost ($ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)

In addition to the estimated savings from limiting enrollment into certain D–SNPs starting in plan year 2027, these provisions require updates to a variety of CMS manual systems.

The finalized change to § 423.38(c)(4) and the finalized provision at § 423.38(c)(35) will create burden for CMS to update MA–PD plan manual chapters, the plan communication user guide (PCUG), and model enrollment notices. Additionally, the MARx system will require coding changes for the finalized amended dual/LIS SEP at § 423.38(c)(4) and finalized integrated care SEP at § 423.38(c)(35). The CMS call center 1–800–MEDICARE will need training on the finalized SEPs to be able to identify beneficiaries eligible for the SEPs. The updates and changes will require two GS–13 staff 20 hours to complete the necessary updates. We estimate the burden for plan year 2025, would be at 40 hours (2 GS–13 * 20 hrs) at a cost of $2,433 (40 hrs * $60.83) for two GS–13 staff to update manual chapters, the PCUG, enrollment notices, and complete coding for MARx. This is a one-time cost that will not create new burden in subsequent years.

The finalized provision at § 422.514(h)(3)(ii) with modification will allow plans to continue operating a PPO and HMO in the same service area but not allow new enrollments of full-benefit dually eligible individuals into the plan (or plans) that are not aligned with the affiliated MCO as described § 422.514(h)(1). This provision will not create new administrative cost for CMS since CMS would use its existing process to suppress these plans from Medicare Plan Finder.

The finalized provision at § 422.530(c)(4)(iii) allowing a crosswalk exception for plans consolidating their D–SNPs will create burden for CMS. The coding to create the crosswalk exception would require one GS–13 10 hours to complete the necessary updates. The burden for plan year 2025, is estimated at 10 hours (1 GS–13 * 10 hrs) at a cost of $608.30 (10 hrs * $60.83) for a GS–13 to complete coding for crosswalk exceptions. This is a one-time cost that will not create new burden in subsequent years. The burden associated with crosswalks and plan consolidation could create additional burden such as breaking plans into

different PBPs or having fewer PBPs to manage in the future. We cannot estimate these actions and associated burden but generally believe they cancel each other out.

3. Effects of Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

We do not estimate any impact on the Medicare Trust Fund as a result of the provisions to permit immediate substitutions of new interchangeable biological products for their reference products or to treat substitutions of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes. New biosimilar biological products are approved or licensed by the FDA and become available on the market at irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. The introduction of biosimilar biological products to the market is relatively recent compared to generic small molecule drugs. We believe there is a potential for savings to the Medicare Trust Fund in the long term as acceptance of biosimilar biological products grows and increased competition drives down costs; however, a number cannot be estimated right now. We received no comments on our estimate and are therefore finalizing without change.

4. Mid-Year Notice of Unused Supplemental Benefits

This proposal would require plans to notify enrollees about any supplemental benefit they have not used during the first half-year of the contract year. We lack data to quantify the effects of this provision. Therefore, we present a qualitative analysis below. The provision has 3 impacts on plans and the MA program.

One impact is the burden to plans to notify enrollees. This burden has been quantified in the Collection of Information in section X. of this finalized rule. The burden consists of: (1) a system update to identify supplemental benefits not utilized by enrollees; and (2) the burden to notify enrollees.

The second impact relates to the intent of the provision, which is to increase utilization of benefits when appropriate. In some cases, this could initially involve a cost to both enrollees for their share of cost sharing, and to the plans for providing the benefit. In assessing the impact, there are several dimensions of impact for which we lack complete data: (1) which supplemental benefits are not being utilized at all by some enrollees; (2) for each plan offering supplemental benefits, how many enrollees do and do not utilize these benefits; (3) how many more enrollees would utilize these benefits as a result of the notification; and (4) what is the range and distribution of the cost to provide these supplemental benefits.

The third impact relates to savings expected from increased utilization. Normally, such savings are considered consequences of a provision and not typically analyzed in an RIA. We use dental and gym benefits to show several complications and possibilities in this analysis.

Enrollees who use their preventive supplemental dental benefits may uncover problems early, thus preventing unnecessary complications. For example, the filling of cavities may prevent a costlier root canal later. Also note that the filling may happen in one plan while the costlier root canal that was prevented refers to a possible event several years later possibly in another plan (or out of pocket for the enrollee).

An interesting subtlety of this example is that enrollees who have preventive dental checkups may do so annually or semi-annually. The effect of the notification might be to increase annual checkups to semi-annual checkups. It is harder to quantify the savings from such a change in frequency.

From discussions with plans, we know that enrollees may incur the cost of a gym membership benefit without utilizing it. The intent of the provision would be to increase gym utilization. In the case of gym benefits the savings from increased prevention is challenging to analyze since different frequencies of gym attendance have different effects on health. An enrollee, for example, who decides to visit the gym only once because of the notification might not have any significant health benefits generating savings; even enrollees who switch to monthly visits may not experience savings. The savings on enrollees who decide to continue gym visits on a regular basis might arise from varied consequences since increased exercise has the potential to ''reduce risk of chronic conditions like obesity, type 2 diabetes, heart disease, many types of cancer, depression and anxiety, and dementia.'' [266]

In summary, this is the type of provision that has a savings impact that can be analyzed only after several years of experience with the provision.

5. Agent Broker Compensation (§ 422.2274)

In the NPRM we proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation;'' and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We also proposed to make conforming edits to the agent broker compensation rules at § 423.2274.

We are finalizing the above provisions as proposed, but with the following modifications.

We are finalizing our proposal to generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs. We are finalizing the policies to set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation,'' and clarify the applicability date of October 1, 2024. And we are finalizing our policy to eliminate the use of administrative payments, with an applicability date of October 1, 2024. In addition, we are finalizing a one-time $100 increase to the FMV compensation rate for agents and brokers to reimburse them for necessary administrative activities.

As explained in the Section X.C.9 of this final rule, as a result of comments we replaced the line-item approach to estimating costs with a holistic cost estimate. This holistic cost estimate was based on the wide range of estimates of current administrative costs provided by stakeholders in response to our solicitation of comments. Additionally, since the finalized $100 flat rate to be paid by plans directly to agent brokers is less than the current administrative payments by plans—which are being eliminated, we regard the costs

[266] *https://www.cdc.gov/chronicdisease/resources/infographic/physical-activity.htm#.*

associated with this provision as a transfer; that is, a portion of the money currently being spent on administrative expenses is going towards the $100 flat rate but is not an additional cost.

The true cost of most administrative expenses can vary greatly from one agent or broker to another and is based in data and contracts that CMS does not have access to, so it would be extremely difficult for us to accurately capture, making a line-item calculation not practicable. This was further reflected in the wide variation among alternate rates posed by commenters, with a few commenters suggesting an alternate rate increase of $50, another $75, while the majority recommended higher rates beginning at $100 and some going as high as $500. Some commenters suggested that we should calculate the compensation increase as a percentage of the base rate, such as 30% or 33% of the current $611 compensation figure.

Considering the complexities involved in balancing the incentives not only between MA organizations and agents, brokers, and other TPMOs, but also balancing incentives between MA and other parts of Medicare, such as Traditional Medicare with PDP or supplemental Medigap plans, we believe that choosing a flat rate for calculating the increase is an appropriate path forward. By taking a flat-rate approach, we are able to create parity among agents, regardless of which plan, plan type, or type of Medicare enrollment they effectuate on behalf of the beneficiary. Given the fact that the administrative payments are intended to cover administrative costs that do not substantially differ based on which plan a beneficiary ultimately enrolls in, the flat rate approach is the best way to achieve our goals.

Several commenters suggested that an increase of $100 would be an appropriate starting point, and reflects the minimum monthly costs of necessary licensing and technology costs. We understand that other commenters recommended an increase of more than $100, including some suggesting an increase of $200 or more. However, we believe, based on the totality of comments, that recommendations for an increase above $100 may have been inflated to include the full price of all technology and systems that are also utilized to effectuate sales in other markets. In addition, it appears that such recommendations may reflect the lost ''bonuses'' and other ''administrative payments'' agents and brokers may previously have received, some of which were beyond the scope and FMV of the services involved in enrolling beneficiaries into MA plans and, therefore, should not have been included under compensation or administrative payments.

6. Enhancing Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

In § 422.626, we proposed to (1) require the QIO instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility or end home health, CORF, or home-based hospice services before the proposed terminate date.

Currently, there is no data collected on the volume of fast-track appeals conducted by MA plans for untimely requests. The QIO conducts appeals for FFS fast-track appeals for untimely requests but does not formally collect data on appeals based on untimely requests from MA enrollees. Thus, the following estimates were speculative given the lack of precise data on the number of the fast-track appeals for untimely FFS requests.

Anecdotal data from the QIOs conducting these fast-track appeals indicates that approximately 2.5 percent of all fee-for-service (FFS) fast-track appeal requests are untimely. In CY 2021 (most recent year available), there were 190,031 MA fast-track appeals to the QIO. Thus, we estimate that approximately 4,751 fast track appeals will be shifted from MA plans to the QIO ($0.025 \times 190{,}031$).

The shift of these untimely appeals from the MA plans to the QIOs will result in an increased burden to QIOs and a reduced burden to MA plans. There is an estimated per case cost for QIOs to conduct these appeals (per the Financial Information and Vouchering System (FIVS) from 5/1/2019–7/31/2023), while MA plans are not specifically reimbursed for this activity. The average QIO appeal of this type takes 1.69 hours at $85.18/hr.

In aggregate we estimate an annual burden of 8,029 hours (4,751 responses * 1.69 hr/response) at a cost of $683,910 ($8{,}029 \text{ hr} \times \$85.18/\text{hr}$). This is being classified as a transfer from MA plans to QIOs.

We were unable to estimate how many new QIO reviews will be conducted under the proposed provision at § 422.626(a)(3) to eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the skilled nursing facility or end home health, CORF, or home-based hospice services before the proposed termination date. No entity tracks how many appeals are not conducted because the enrollee stopped the services at issue before the last day of coverage. Further, because this provision has never existed for FFS, we have no basis from which to derive an estimate.

We received no comments on our estimate and are therefore finalizing without change.

7. Part D Medication Therapy Management (MTM) Program Targeting Requirements (§ 423.153)

We proposed to revise § 423.153(d)(2) to: (1) codify the current nine 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 eight to five 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 five generic drugs ($1,004 in 2020). We estimated 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 proposed to codify as core chronic diseases are more prevalent among underserved populations, including minority and lower income populations. As a result, we anticipated that our proposed changes would increase eligibility rates among those populations.

We did not receive any comments on this section of the proposed rule. After consideration of the comments we did receive, we are finalizing our proposal with modifications. We are finalizing the requirement that sponsors include all core chronic conditions in their targeting criteria (the current nine core

chronic diseases, as well as HIV/AIDS), for a total of 10 core chronic conditions. Plan sponsors would also be required to include all Part D maintenance drugs in their targeting criteria. We are not finalizing the change to the maximum number of Part D drugs sponsors may require in their targeting criteria (remains at eight), and for alignment, modifying the calculation of the MTM cost threshold to be commensurate with the average annual cost of eight generic Part D drugs. This would result in a program size of 7,065,385 (or 13 percent of the Part D enrollees using 2022 data) compared to the current 3,599,356 (7 percent of Part D enrollees using actual 2022 MTM enrollment). The changes would allow us to address specific gaps identified in MTM program eligibility by reducing marked variability across plans and ensuring more equitable access to MTM services; better align with Congressional intent while focusing on more beneficiaries with complex drug regimens; and keep the program size increase manageable. The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce as a whole. A moderate expansion also offers opportunities to focus on quality through the development of new, outcomes-based MTM measures, promoting consistent, equitable, and expanded access to 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 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. 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 changes is addressed in the Collection of Information section (section X.) of this final rule in the ICR section for MTM targeting criteria.

F. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this final 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, traditional categories of alternative analysis such as different compliance dates, different enforcement methods, different levels of stringency, as outlined in section C of OMB's Circular A–4, are not fully relevant since the provision is already being complied with adequately. Consequently, alternative analysis is not provided for these provisions.

1. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514)

We are finalizing a reduction to the threshold for D–SNP look-alikes from 80 percent to 60 percent over a 2-year period. We considered an alternative proposal to lower the D–SNP look-alike threshold to 60 percent in 1 year, allowing an earlier phase-out of these non-SNP MA plans. But we are finalizing the more incremental approach to minimize disruptions to dually eligible individuals and allow plans and CMS more time to operationalize these transitions.

We considered and solicited comment on an alternative to our proposal that would eliminate the proposed 70 percent threshold for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would:

- Apply the 60 percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and subsequent plan years.

Relative to our final provision, this alternative would have given plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment based on January 2024 enrollment data one additional year to apply for a new D–SNP or service area expansion to an existing D–SNP, such that these plans could transition enrollees into a D–SNP for plan year 2026. The alternative would have balanced the additional year using the existing 80 percent enrollment threshold to identify prohibited D–SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicited comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D–SNPs and to encourage and incentivize enrollment in integrated care plans.

Among the factors we considered related to the alternative is the extent to which plans with 70 percent or more dually eligible enrollment in plan year 2024 expect to be able to establish a D–SNP in the same service area as the D–SNP look-alike if given an additional year (that is, 2026) to transition enrollees. Based on 2023 plan year data, approximately two-thirds of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals already have a D–SNP under the same MA organization with the vast majority of those D–SNPs having a service area that covers the service area as the non-SNP MA plan. The other approximately one-third of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals do not have a D–SNP in the same service area in plan year 2023. If given an additional year, these MA organizations would have had more time in which to establish D–SNPs in the same service areas as non-SNP MA plans and transition the enrollees into a D–SNP.

We are not finalizing any of these alternative policies, and instead are finalizing this provision as proposed, as discussed in section VIII.J. of this final rule.

2. Part D Medication Therapy Management (MTM) Program Targeting Criteria (§ 423.153)

We considered two alternatives to our original 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 did not receive any comments in response to the specific alternatives considered in the proposed rule; therefore, we did not pursue finalizing either of these alternatives. We are instead finalizing the proposed changes with modifications to the Part D MTM program eligibility requirements as discussed in section III.E. of this final rule which includes our proposed changes related to chronic diseases, retains the current maximum number of Part D drugs a sponsor may require for MTM program enrollment at 8 drugs, requires sponsors to include all Part D maintenance drugs in their targeting criteria, and establishes a cost threshold commensurate with the average annual cost of 8 generic maintenance drugs. The changes we are finalizing allows us to be responsive to commenters' concerns regarding the potential impact of reducing the maximum number of Part D drugs from eight to five to maintain, about program size, and the ability to administer effective MTM services, while still addressing the barriers to eligibility posed by the increasingly restrictive plan criteria (for example, by targeting select core chronic diseases or drugs) and the high cost threshold, which were identified in our analysis as the main drivers of reduced eligibility rates for MTM.

G. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*) in Table K4, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this final rule for calendar years 2025 through 2034. Table K4 is based on Tables K–5a Table K5b which list savings and costs by provision and year. Tables K4, K5a and K5b list annual costs as positive numbers and savings as positive numbers. As can be seen, expenditures of the Medicare Trust Fund are reduced by about $200 million annually, the savings arising from increased efficiencies in operating Dual Eligibles Special Needs Plans. This is offset by the approximately $224 million annual cost of this rule. The major contributors to this annualized cost are a variety of mailings and notifications. Minor seeming discrepancies in totals in Tables K4, K5a, and K5b reflect use of underlying spreadsheets, rather than intermediate rounded amounts.

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TABLE K4: ACCOUNTING TABLE ($ MILLIONS)*

Item	Annualized at 3%	Annualized at 7%	Period	Who is affected
Net Annualized Monetized Costs	224.1	224.1	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Savings	$4.0	$4.0	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Costs	$228.1	$228.1	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Transfers	214.1	192.8	CYs 2025–2034	Reduced dollar spending of the Medicare Trust Fund to Medicare Advantage Plans and Plan sponsors who are spending less to buy the same benefits

* The savings and cost are expressed with positive numbers. For example, at 3%, this final rule annually costs $228.1 million but saves $4.0 million resulting in a net cost of $224.1 million (errors are due to rounding). The transfers, listed as positive numbers, reflect savings, dollar reductions to the Medicare Trust Fund.

The following Tables K5a and K5b summarize costs, and savings by provision and year, and form a basis for the accounting Table K4. In Tables K5a and K5b, annual costs and savings are expressed as positive numbers and, except for the last two rows, are true costs and savings reflecting increases or decreases in consumption of services and goods. However, the provisions presenting impacts of increasing enrollment for D–SNPs on Part C and Part D which affect the Medicare Trust Fund are transfers reflecting buying the same goods and services with greater efficiency. These transfers are expressed as positive numbers and reflect reduced dollar spending to the Trust Fund, that is savings. The provision enhancing enrollee appeal rights is a transfer from MA administrative costs to QIO costs. The 10-year aggregate impacts in the right-most column use positive numbers to reflect costs and negative numbers to reflect savings, Tables K5a and K5b combine related provisions. For example, all provisions in the COI summary table related to PACE are combined into one line item in the RIA.

TABLE K5a: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR *

Item	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Total Savings	4.0			4.0			4.0			4.0			4.0		
Total Costs		229.4			227.9			227.9			227.9			227.9	
Aggregate Total	225.4			223.9			223.9			223.9			223.9		
Savings of the Medicare Trust Fund			0.7			0.7			13.3			25.6			37.6
DMP	3.0			3.0			3.0			3.0			3.0		
Multi Language Inserts		0.1			0.0			0.0			0.0			0.0	
Formulary Provisions	1.0			1.0			1.0			1.0			1.0		
Mid-Year Notification of unused Supplemental Benefits		23.7			23.7			23.7			23.7			23.7	
Utilization Committee		1.0			0.0			0.0			0.0			0.0	
SSBCI Provision		7.0			7.0			7.0			7.0			7.0	
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1	
PACE Provisions		2.1			1.9			1.9			1.9			1.9	
Increasing D-SNP Enrollment, Paperwork burden		0.2			0.0			0.0			0.0			0.0	
Involuntary Disenrollment from D-SNPS		0.5			0.5			0.5			0.5			0.5	
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7	
MTM		192.7			192.7			192.7			192.7			192.7	
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3	
Increasing D-SNP Enrollment, Part C									5.5			10.9			15.9
Increased Enrollment in D-SNPS, Part D									7.0			13.9			21.1
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7

*Table K5a is continued in Table K5b

TABLE K5b: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR (Continued from Table K5a)*

Item	2030 Savings	2030 Costs	2030 Transfers	2031 Savings	2031 Cost	2031 Transfers	2032 Savings	2032 Cost	2032 Transfers	2033 Savings	2033 Cost	2033 Transfers	2034 Savings	2034 Cost	2034 Transfers	Raw 10 Year Totals
Total Savings	4.0			4.0			4.0			4.0			4.0			40.1
Total Costs		227.9			227.9			227.9			227.9			227.9		2280.6
Aggregate Total	223.9			223.9			223.9			223.9			223.9			2240.6
Savings of the Medicare Trust Fund			406.3			421.1			440.1			470.0			493.9	2,307.8
DMP	3.0			3.0			3.0			3.0			3.0			-30.5
Multi Language Inserts		0.0			0.0			0.0			0.0			0.0		0.1
Formulary Provisions	1.0			1.0			1.0			1.0			1.0			-9.6
Mid-Year Notification of unused Supplemental Benefits		23.7			23.7			23.7			23.7			23.7		236.9
Utilization Committee		0.0			0.0			0.0			0.0			0.0		1.1
SSBCI Provision		7.0			7.0			7.0			7.0			7.0		70.0
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1		0.6
PACE Provisions		1.9			1.9			1.9			1.9			1.9		19.2
Increasing D-SNP Enrollment, Paperwork burden		0.0			0.0			0.0			0.0			0.0		0.2
Involuntary Disenrollment from D-SNPS		0.5			0.5			0.5			0.5			0.5		5.1
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7		17.2
MTM		192.7			192.7			192.7			192.7			192.7		1927.2
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3		3.1
Increasing D-SNP Enrollment, Part C			170.8			175.3			180.3			195.7			206.9	961.4
Increased Enrollment in D-SNPS, Part D			234.8			245.0			259.2			273.7			286.3	1340.9
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7	6.8

NOTES:

- Positive numbers in the annual cost columns reflect costs while positive numbers in the annual savings columns reflect savings. The aggregate row subtracts the savings from the cost and therefore lists the aggregate total as a cost expressed as a positive number. The raw total column (over 10 years) expresses costs as positive numbers and savings as negative numbers.
- Two-line items effect the Trust Fund: Increased Enrollment in D-SNPs, Part C, and Increased Enrollment in D-SNPs, Part D. Over 10 years they save, $961, and $1,341 million respectively.
- When the aggregate of line items for a provision is below $50,000, for example the paperwork burden of $4929 associated with the provision for network adequacy of behavioral health, or the cost to CMS staff to perform certain tasks listed in this section, they were not included in the table (since they do not have an effect on numbers). However, when the aggregate of several provisions rounded to at least $0.1 million it was included.
- Line items belonging to one class of provisions in the COI Summary table are included under one line item in this RIA summary table. For example, the three line items contributing to the paper burden of Medication Therapy Management (MTM) are added together in one line in this RIA Summary table.

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H. Conclusion

In aggregate this final rule combines both savings and costs. Three provisions reduce spending by the Medicare Trust Fund: (1) the effect on Part C plans from the provisions designed to increase the

percentage of dually eligible managed care enrollees who are enrolled in integrated D–SNPs; (2) the effect on Part D plans from these D–SNP provisions and (3) enhancing enrollee appeal rights. Over a 10-year period they reduce spending of the Medicare Trust Fund of $961, $1,341, and $6.8 million respectively for a combined savings of $2.3 billion. These savings are offset by various paperwork burden and some minor savings which in aggregate over 10 years cost $2.2 billion. The major drivers of cost are the mailings to enrollees regarding unused supplemental benefits and medication therapy management (MTM). The provisions for the Drug Management Program reduce paperwork burden by $3 million annually saving $30.5 million over 10 years.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 29, 2024.

List of Subjects

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), 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.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. 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.

■ 2. Section 417.460 is amended by revising paragraphs (c)(3), (e)(2), (e)(4), and adding (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 does all of the following:

(i) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(ii) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(iii) Shows good cause for failure to pay.

(iv) Pays all overdue premiums or other charges within 3 calendar months after the disenrollment date.

(v) Establishes 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.* (i) 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.

(ii) 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 before submitting the request for disenrollment to CMS.

(i) 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.

(A) 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.

(B) 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 to provide an opportunity for the individual to cease their behavior.

(ii) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP requests CMS permission to involuntarily disenroll the enrollee. This notice must be provided before submission of the request to CMS.

* * * * *

■ 3. Section 417.472 is amended by adding paragraph (l) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(l) *Resolution of complaints in the complaints tracking module.* The HMO or CMP must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the HMO or CMP within the required timeframes. References to the MA organization or MA plan in those regulations shall be read as references to the HMO or CMP.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 4. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 5. Section 422.2 is amended by—

■ a. Revising the definition of ''Basic benefits'';
■ b. Adding the definition of ''Chronic condition special needs plan (C–SNPs)'', ''Facility-based institutional special needs plan (FI–SNP)'', ''Hybrid institutional special needs plan (HI–SNP)'', ''Institutional-equivalent special needs plan (IE–SNP)'', ''Institutional special needs plan (I–SNP)'', and ''Network-based plan'' in alphabetical order; and
■ c. Revising the definition of ''Severe or disabling chronic condition''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means Part A and Part B benefits except—

(1) Hospice services; and

(2) Beginning in 2021, organ acquisitions for kidney transplants, including costs covered under section 1881(d) of the Act.

* * * * *

Chronic condition special needs plan (C–SNPs) means an 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).

* * * * *

Facility-based Institutional special needs plan (FI–SNP) means a type of I–SNP that—

(1) Restricts enrollment to MA eligible individuals who meet the definition of institutionalized;

(2) Must own or contract with at least one institution, specified in the definition of institutionalized in this section, for each county in the plan's service area; and

(3) 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—

(1) 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; and

(2) 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:

(1) IE–SNP.

(2) HI–SNP.

(3) FI–SNP.

* * * * *

Network-based plan—

(1) Means—

(i) A coordinated care plan as specified in § 422.4(a)(1)(iii);

(ii) A network-based MSA plan; or

(iii) A section 1876 reasonable cost plan; and

(2) 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 sections 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:

(i) Spinal cord injuries.
(ii) Paralysis.
(iii) Limb loss.
(iv) Stroke.
(v) 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.
* * * * *

■ 6. 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.
* * * * *

■ 7. Section 422.52 is amended by—
■ a. Revising paragraph (b)(2);
■ b. Revising paragraph (f); and
■ c. Adding paragraph (g).
The revision and additions read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *
(b) * * *
(2) Meet the eligibility requirements for that specific SNP, including any additional eligibility requirements established in the State Medicaid agency contract (as described at § 422.107(a)) for dual eligible special needs plans; and
* * * * *
(f) Establishing eligibility for enrollment. (1) For enrollments into an SNP that exclusively enrolls individuals that have severe or disabling chronic conditions (C–SNP), the organization must contact the applicant's current health care provider, who is a physician as defined in section 1861(r)(1) of the Act, physician assistant as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c) of this chapter, or a nurse practitioner as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii) of this chapter to confirm that the applicant has the qualifying condition(s). The organization must obtain this information in one of the following two ways described in paragraph (f)(1)(i) or (ii) of this section:
(i) Contact the current health care provider or current health care provider's office and obtain verification of the applicant's condition(s) prior to enrollment in a form and manner authorized by CMS.
(ii) Through an assessment with the enrollee using a pre-enrollment qualification assessment tool (PQAT) where the assessment and the information gathered are verified (as described in paragraph (f)(1)(iii) of this section) before the end of the first month of enrollment in the C–SNP. Use of a PQAT requires the following:
(A) The PQAT must do all of the following:
(*1*) Include clinically appropriate questions relevant to the chronic condition(s) on which the C–SNP focuses.
(*2*) Gather sufficient reliable evidence of having the applicable condition using the applicant's past medical history, current signs or symptoms, and current medications.
(*3*) Include the date and time of the assessment completion if done face-to-face with the applicant, or the receipt date if the C–SNP receives the completed PQAT by mail or by electronic means (if available).
(*4*) Include a signature line for and, once completed, be signed by the current health care provider specified in paragraph (f)(1) of this section to confirm the individual's eligibility for C–SNP enrollment.
(B) The C–SNP conducts a post-enrollment confirmation of each enrollee's information and eligibility by having the completed PQAT reviewed and signed by the enrollee's current health care provider as specified in paragraph (f)(1) of this section.
(C) The C–SNP must include the information gathered in the PQAT and used in this verification process in its records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.
(D)(*1*) The C–SNP tracks the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment.
(*2*) Data and supporting documentation are made available upon request by CMS.
(E) If the organization does not obtain verification of the enrollees' required chronic condition(s) by the end of the first month of enrollment in the C–SNP, the organization must—
(*1*) Disenroll the enrollee as of the end of the second month of enrollment; and
(*2*) Send the enrollee notice of the disenrollment within the first 7 calendar days of the second month of enrollment.
(F) The organization must maintain the enrollment of the individual if verification of the required condition(s) is obtained at any point before the end of the second month of enrollment.
(iii) Prior to enrollment, the PQAT must be completed by the enrollee, completed by the enrollee's current health care provider, or administered with the enrollee by a provider employed or contracted by the plan. The PQAT must be signed by the enrollee's current health care provider as verification and confirmation that the enrollee has the severe or disabling chronic condition required to be eligible for the C–SNP, which may be done post-enrollment.
(2) [Reserved]
(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.

■ 8. Section 422.60 is amended by—
■ a. Revising paragraph (a)(1); and
■ b. Adding paragraphs (a)(3), (h) and (i).
The revision and additions read as follows:

§ 422.60 Election process.

(a) * * *
(1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraphs (a)(2) and (3) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the

circumstances described in § 422.62(b)(1) through (b)(4).

* * * * *

(3) Dual eligible special needs plans must limit enrollments to those individuals who meet the eligibility requirements established in the state Medicaid agency contract, as specified at § 422.52(b)(2).

* * * * *

(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.

* * * * *

(i) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 9. Section 422.62 is amended by—

■ a. Revising paragraphs (a)(1)(i), (a)(4), (b)(2), and (b)(18) introductory text;

■ b. Redesignating paragraphs (b)(18)(i) through (b)(18)(iii) as paragraphs (b)(18)(ii) through (b)(18)(iv), respectively; and

■ c. Adding new paragraph (b)(18)(i).

The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(1) * * *

(i) The last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B; or

* * * * *

(4) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make.

(i) Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from Original Medicare to an MA plan.

(ii) The open enrollment period for institutionalized individuals ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of ''institutionalized'' in § 422.2.

* * * * *

(b) * * *

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior. 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 an SEP to make an 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 the 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 is 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. 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.

* * * * *

■ 10. 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.

(*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.

* * * * *

■ 11. Section 422.68 is amended by adding paragraph (g) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(g) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the MA organization must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective

date, the MA organization must attempt to contact the beneficiary and must document its attempts.

(2) If the MA organization is unable to obtain the beneficiary's desired enrollment effective date, the MA organization must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the MA organization is unable to obtain the beneficiary's desired disenrollment effective date, the MA organization must assign an election period that results in the earliest disenrollment.

■ 12. Section 422.74 is amended by—

■ a. Adding paragraph (b)(2)(vi);

■ b. Revising paragraphs (c) and (d)(1)(i)(B)(*1*);

■ c. Revising paragraph (d)(1)(v)

■ e. Revising paragraphs (d)(2)(iii) and (d)(2)(iv);

■ f. Adding paragraph (d)(2)(vii);

■ g. Revising paragraphs (d)(4)(i) and (d)(4)(iv);

■ i. Adding paragraphs (d)(4)(ii)(A), adding and reserving (d)(4)(ii)(B) and adding (d)(4)(iii)(F);

■ j. Redesignating paragraph (d)(8) as (d)(9);

■ k. Adding new paragraph (d)(8);

■ l. Adding paragraph (d)(10); and

■ m. Revising paragraph (e)(1).

The addition and revisions 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), (b)(2)(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) of this section 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 does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date;

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment;

(C) Shows good cause for failure to pay within the initial grace period;

(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.* (A) The MA organization must—

(*1*) 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.

(*2*) 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.

(B) 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—

(A) 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.

(B) May request from CMS the ability to decline future enrollment by the individual.

(C) Must submit to CMS—

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section;

(*2*) Any documentation received by the beneficiary;

(*3*) Dated copies of the notices required in paragraph (d)(2)(vii) of this section.

* * * * *

(vii) *Required notices.* The MA organization must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) 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.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the organization must begin the process again.

(*2*) 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.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the MA organization requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 422.74(c).

* * * * *

(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 U.S. 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 U.S. 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 all of the following:

(A) The disenrollment effective date.

(B) A description of eligibility for the SEP described in § 422.62(b)(11).

(C) If applicable all of the following:

(*1*) Information regarding the period of deemed continued eligibility authorized by § 422.52(d).

(*2*) The duration of the period of deemed continued eligibility.

(*3*) The consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final notice of involuntary disenrollment must be sent as follows:

(A) Within 3 business days following the disenrollment effective date, which is either—

(*1*) The last day of the period of deemed continued eligibility, if applicable; or

(*2*) A minimum of 30 days after providing the advance notice of disenrollment.

(B) Before submission of the disenrollment to CMS.

(iv) The final notice of involuntary disenrollment 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 § 422.74(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) through (iii), (b)(2)(ii) or (b)(2)(vi) of this section is deemed to have elected original Medicare.

* * * * *

■ 13. Section 422.100 is amended by adding paragraph (o) to read as follows:

§ 422.100 General requirements.

* * * * *

(o) *Cost sharing standards for D–SNP PPOs.* Beginning on or after January 1, 2026, an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan must establish cost sharing for out-of-network services that—

(1) Complies with the limits described in paragraph (f)(6) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans; and

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding paragraph (j)(1)(i)(C)(*2*) and the last sentence of paragraph (j)(1)(i)(E) of this section.

■ 14. Section 422.101 is amended by—

■ a. Adding paragraph (f)(2)(vi);

■ b. Revising paragraph (f)(3)(iii); and

■ c. Adding (f)(3)(iv).

The additions and revisions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(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 is only approved if each element of the model of care meets the minimum benchmark and the model of care meets the aggregate minimum benchmark.

(A) An MOC for a C–SNP that receives a passing score is approved for 1 year.

(B)(*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.

(*3*) An MOC for an I–SNP or DSNP 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 sponsoring 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) C–SNPs, D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D–SNPs and I–SNPs must submit updates and corrections to their NCQA approved MOC between June 1st and November 30th of each calendar year if the I–SNP or D–SNP wishes to make any of the following revisions:

(*1*) Substantial changes in policies or procedures pertinent to any of the following:

(*i*) The health risk assessment (HRA) process.

(*ii*) Revising processes to develop and update the Individualized Care Plan (ICP).

(*iii*) The integrated care team process.
(*iv*) Risk stratification methodology.
(*v*) 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).
(*5*) Changes to quality metrics used to measure performance.
(C) NCQA only reviews 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 reviewed and approved the off-cycle MOC changes. NCQA does not rescore the MOC during the off-cycle review of changes to the MOC, but changes are reviewed and determined by NCQA to be either ''Acceptable'' or ''Non-acceptable.'' ''Acceptable'' means that the changes have been approved by NCQA and the MOC has been updated; ''Non-acceptable'' means the changes have been rejected by NCQA and the MOC has not been changed. If NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved.
(E) Successful revision of the MOC under paragraph (f)(3)(iv)(B) of this section does not change the MOC's original period of approval.
(F) C–SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.
(G) When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.

■ 15. Section 422.102 is amended by revising paragraphs (f)(1)(i)(A)(*2*), (f)(3), (f)(4) and adding paragraph (f)(5) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *
(f) * * *
(1) * * *
(i) * * *
(A) * * *
(*2*) Has a high risk of hospitalization or other adverse health outcomes; and
* * * * *

(3) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.
(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.
(ii) An MA organization must include in its bibliography a comprehensive list of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered, including any available negative evidence and literature.
(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.
(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:
(i) Have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in *paragraph (f)(1)(i)* of this section.
(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.
(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and
(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this paragraph and the objective criteria on which the written policies are based.
(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.
(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.
(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.
(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422 subpart F nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

■ 16. Section 422.111 is amended by—
■ a. Revising paragraph (h)(1)(iv)(B); and
■ b. Adding paragraph (l).

The revision and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *
(h) * * *
(1) * * *
(iv) * * *
(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.
* * * * *

(l) *Mid-year notice of unused supplemental benefits.* Beginning January 1, 2026, MA organizations must send notification annually, no sooner than June 30 and no later than July 31, to each enrollee with unused supplemental benefits consistent with the requirements of § 422.2267(e)(42).

■ 17. 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 as defined in § 422.2.

* * * * *

■ 18. Section 422.116 is amended by—

■ a. Adding paragraph (b)(2)(xiv);

■ b. In paragraph (d)(2), amend Table 1 by revising the column headings and adding an entry for ''Outpatient Behavioral Health'' in alphabetical order;

■ c. Adding paragraph (d)(5)(xv);

■ d. In paragraph (f)(1) introductory text, removing the phrase ''both of the following occur'' and adding in its place the phrase ''either of the following occur'';

■ e. Revising paragraph (f)(1); and

■ f. Adding paragraph (f)(2)(iv) and (f)(3).

The additions and revisions read as follows:

§ 422.116 Network adequacy.

(b) * * *

(2) * * *

(xiv) Outpatient behavioral health, which can include marriage and family therapists (as defined in section 1861(lll) of the Act), mental health counselors (as defined in section 1861(lll) of the act), opioid treatment programs (as defined in section 1861(jjj) of the act), community mental health centers (as defined in section 1861(ff)(3)(b) of the act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including psychotherapy or prescription of medication for substance use disorders; physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

(A) To be considered as regularly furnishing behavioral health services for the purposes of this regulation, a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) must have furnished specific psychotherapy or medication prescription services (including, buprenorphine and methadone, for substance use disorders) to at least 20 patients within a 12-month period. CMS will identify, by detailed descriptions or Healthcare Common Procedure Coding System (HCPCS) code(s), the specific services in the HSD Reference File described in paragraph (a)(4)(i) of this section.

(B) To determine that a PA, NP, or CNS meets the standard in paragraph (b)(2)(xiv)(A) of this section, an MA organization must do all of the following:

(*1*) On an annual basis, independently verify that the provider has furnished such services within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

(*2*) If there is insufficient evidence of past practice by the provider, have a reasonable and supportable basis for concluding that the provider will meet the standard in paragraph (b)(2)(xiv)(A) of this section in the next 12 months.

(*3*) Submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the provider meets the standard in paragraph (b)(2)(xiv)(A) of this section.

* * * * *

(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
* * *										
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100
* * *										

* * * * *

(5) * * *

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

* * * * *

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when either paragraph (f)(1)(i) or (f)(1)(ii) of this section is met:

(i)(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and

(B) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(ii)(A) A facility-based Institutional-Special Needs Plan (I–SNP) is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care; or

(B) A facility-based I–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

(2) * * *

(iv) As applicable, the facility-based I–SNP submits:

(A) Evidence of the inability to contract with certain specialty types required under this section due to the way enrollees in facility-based I–SNPs receive care; or

(B) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the

facility-based I–SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

(3) Any MA organization that receives the exception provided for facility-based I–SNPs must agree to offer only facility-based I–SNPs under the MA contract that receives the exception.

■ 19. Section 422.125 is added to read as follows:

§ 422.125 Resolution of complaints in a Complaints Tracking Module.

(a) *Definitions.* For the purposes of this section, the terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular MA organization in the Complaints Tracking Module.

Complaints Tracking Module means an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaints.* The MA organization must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The MA organization must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The MA organization must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under §§ 422.564(f) or 422.630(d), if a complaint is also a grievance within the scope of §§ 422.564 or 422.630 and the requirements for an extension of the time to provide a response in §§ 422.564(e)(2) or 422.630(e)(2) are met, the MA organization may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 422.564, 422.630, or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the MA organization must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.:* Regardless of the type of complaint received, the MA organization must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

■ 20. Section 422.137 is amended by adding paragraphs (c)(5), (d)(6), and (7) to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee

* * * * *

(c) * * *

(5) Beginning January 1, 2025, include at least one member with expertise in health equity. Expertise in health equity includes educational degrees or credentials with an emphasis on health equity; experience conducting studies identifying disparities amongst different population groups; experience leading organization-wide policies, programs, or services to achieve health equity; or experience leading advocacy efforts to achieve health equity.

(d) * * *

(6) Beginning in 2025, annually conduct a health equity analysis of the use of prior authorization.

(i) The final report of the analysis must be approved by the member of the committee with expertise in health equity before it is publicly posted.

(ii) The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:

(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.

(B) Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(iii) The analysis must use the following metrics, calculated for enrollees with the specified social risk factors and enrollees without the specified social risk factors, to conduct the analysis at the plan level using data from the prior contract year regarding coverage of items and services excluding data on drugs as defined in § 422.119(b)(1)(v):

(A) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(B) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(C) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(D) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(E) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(F) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

(7) By July 1, 2025, and annually thereafter, publicly post the results of the health equity analysis of the utilization management policies and procedures on the plan's website meeting the following requirements:

(i) In a prominent manner and clearly identified in the footer of the website.

(ii) Easily accessible to the general public, without barriers, including but not limited to ensuring the information is accessible:

(A) Free of charge.

(B) Without having to establish a user account or password.

(C) Without having to submit personal identifying information.

(iii) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(iv) Include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

■ 21. Section 422.164 is amended by—

■ a. Revising paragraph (d)(1)(v);

■ b. Revising and republishing (g)(1)(iii)

■ d. Adding paragraph (h)(3).

The revisions and addition read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(g) * * *

(1) * * *

(iii) For the appeals measures, CMS uses statistical criteria to estimate the percentage of missing data for each contract using data from MA organizations, the independent review entity (IRE), or CMS administrative sources to determine whether the data at the IRE are complete. CMS uses scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A)(*1*) The data reported by the MA organization on appeals, including the number of reconsiderations requested, denied, upheld, dismissed, or otherwise disposed of by the MA organization, and data from the IRE or CMS administrative sources, that align with the Star Ratings year measurement period are used to determine the scaled reduction.

(*2*) If there is a contract consolidation as described at § 422.162(b)(3), the data described in paragraph (g)(1)(iii)(A)(*1*) of this section are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

(B) [Reserved]

(C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data is a four-star reduction.

(D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

(*1*) 20 percent, 1 star reduction.

(*2*) 40 percent, 2 star reduction.

(*3*) 60 percent, 3 star reduction.

(*4*) 80 percent, 4 star reduction.

(E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.

(F) [Reserved]

(G) The scaled reduction is applied after the calculation for the appeals measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.

(H) The Part C calculated error is determined using 1 minus the quotient of the total number of cases received by the IRE that were supposed to be sent and the total number of cases that should have been forwarded to the IRE. The total number of cases that should have been forwarded to the IRE is determined by the sum of the partially favorable (adverse) reconsiderations and unfavorable (adverse) reconsiderations for the applicable measurement year.

(I) [Reserved]

(J) [Reserved]

(K) Contracts are subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(*1*) The calculated error rate is 20 percent or more.

(*2*) The number of cases not forwarded to the IRE is at least 10 for the measurement year.

(L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures.

(2) * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), an MA organization may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 22. Section 422.166 is amended by—

■ a. Revising paragraph (e)(2);

■ b. Revising paragraph (f)(2)(i)(B); and

■ c. Adding paragraphs (f)(3)(viii)(A) and (B).

The revisions and addition read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(e) * * *

(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, a new or substantively updated measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(*2*) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(*3*) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(*4*) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

* * * * *

(3) * * *

(viii) * * *

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 23. 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 must 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.

* * * * *

■ 24. Section 422.260 is amended by—
■ a. Revising paragraphs (c)(1)(i), (c)(2)(v), and (c)(2)(vii);
■ 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.

* * * * *

(vii) After the hearing officer's decision is issued to the MA organization and the CMS Administrator, the hearing officer's decision is subject to review and modification by the CMS Administrator within 10 business days of issuance. If the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding.

* * * * *

(3) * * *

(iii) The MA organization may not request a review based on data inaccuracy for the following data sources:

(A) HEDIS.

(B) CAHPS.

(C) HOS.

(D) Part C and D Reporting Requirements.

(E) PDE.

(F) Medicare Plan Finder pricing files.

(G) Data from the Medicare Beneficiary Database Suite of Systems.

(H) Medicare Advantage Prescription Drug (MARx) system.

(I) 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 by a different MA organization, 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.

* * * * *

■ 25. Section 422.310 is amended by—
■ a. Revising paragraphs (f)(1)(vi) and (f)(1)(vii); and
■ b. Adding new paragraph (f)(3)(v).

The revisions and addition read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *

(1) * * *

(vi) To conduct evaluations and other analysis to support the Medicare and Medicaid programs (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare and Medicaid programs;

* * * * *

(3) * * *

(v) CMS determines that releasing data to State Medicaid agencies before reconciliation for the purpose of coordinating care for dually eligible individuals is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

■ 26. Section 422.311 is amended by—
■ a. Revising paragraph (a);
■ b. Revising paragraph (c)(5)(ii)(B);
■ c. Removing paragraph (c)(5)(ii)(C);
■ d. Revising paragraph (c)(5)(iii);
■ e. Adding paragraph (c)(5)(iv);
■ f. Revising paragraphs (c)(6)(i)(A) and (c)(6)(iv)(B);
■ g. Adding paragraph (c)(6)(v);
■ h. Revising paragraph (c)(7)(ix);
■ i. Revising paragraphs (c)(8)(iii), (c)(8)(iv), (c)(8)(v), and (c)(8)(vi); and
■ j. Adding paragraphs (c)(8)(vii) and (c)(9).

The revisions and additions read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations is conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

* * * * *

(c) * * *

(5) * * *

(ii) * * *

(B) Whether the MA organization requests a payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements. MA organizations will forgo their medical record review determination appeal if they choose to file only a payment error calculation appeal because medical record review determinations need to be final prior to adjudicating a payment error calculation appeal.

(iii) For MA organizations that intend to appeal both the medical record

review determination and the RADV payment error calculation, an MA organization's request for appeal of its RADV payment error calculation may not be filed and will not be adjudicated until—

(A) The administrative appeal process for the RADV medical record review determinations filed by the MA organization has been exhausted; or

(B) The MA organization does not timely request a RADV medical record review determination appeal at the hearing stage and/or the CMS Administrator review stage, as applicable.

(iv) An MA organization whose medical record review determination appeal has been completed as described in paragraph (c)(5)(iii) of this section has 60 days from the date of issuance of a revised RADV audit report, based on the final medical record review determination, to file a written request with CMS for a RADV payment error calculation appeal. This request for RADV payment error calculation appeal must clearly specify where the Secretary's RADV payment error calculation was erroneous, what the MA organization disagrees with, and the reasons for the disagreements.

(6) * * *

(i) * * *

(A) Any and all HCC(s) that the Secretary identified as being in error that the MA organization wishes to appeal.

* * * * *

(iv) * * *

(B) The reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x).

* * * * *

(v) *Computations based on reconsideration official's decision.* (A) Once the reconsideration official's medical record review determination decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the reconsideration official's payment error calculation decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(7) * * *

(ix) *Computations based on Hearing Officer's decision.* (A) Once the hearing officer's medical record review determination decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the hearing officer's payment error calculation decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(8) * * *

(iii) After reviewing a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.

* * * * *

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision; and

* * * * *

(v) The CMS Administrator renders his or her final decision in writing within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

* * * * *

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not decline to review or elect to review within 90 days of the date of the receipt of either the MA organization or CMS's request for review (whichever is later); or

(C) Does not make a decision within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

* * * * *

(vii) *Computations based on CMS Administrator decision.* (A) Once the CMS Administrator's medical record review determination decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the CMS Administrator's payment error calculation decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised and final RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(9) *Final agency action.* In cases when an MA organization files a payment error calculation appeal subsequent to a medical record review determination appeal that has completed the administrative appeals process, the medical record review determination appeal final decision and the payment error calculation appeal final decision will not be considered a final agency action until the payment error calculation appeal has completed the administrative appeals process and a final revised audit report superseding all prior RADV audit reports has been issued to the appellant MA organization.

* * * * *

■ 27. Section 422.500(b) is amended by adding the definitions of ''Final settlement adjustment period'', ''Final settlement amount'', and ''Final settlement process'' in alphabetical order 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, nonrenewed, 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 (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 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 is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

■ 28. Section § 422.502 is amended by—

■ a. Adding paragraph headings for paragraphs (a)(1) and (a)(2) and adding paragraph (a)(3);

■ b. Revising paragraphs (b)(1)(i)(A), (B), and (C);

■ c. Removing paragraphs (b)(1)(i)(E)(*2*)(*A*) and (*B*).

The additions and revisions read as follows.

§ 422.502 Evaluation and determination procedures.

* * * * *

(a) * * *

(1) *Information used to evaluate applications.* * * *

(2) *Issuing application determination.* * * *

(3) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 422.502(c) 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.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) Was under intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(a)(14).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

* * * * *

■ 29. Section 422.503 is amended by adding paragraph (b)(8) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(8) Not newly offer a dual eligible special needs plan that would result in noncompliance with § 422.514(h).

* * * * *

■ 30. Section 422.504 is amended by revising paragraph (a)(15) and adding paragraphs (a)(20) and (a)(21) to read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) As described in § 422.125 of this part, address and resolve complaints received by CMS against the MA organization in the Complaints Tracking Module.

* * * * *

(20) To comply with the requirements established in § 422.514(h).

* * * * *

(21) Not to establish additional MA plans that are not facility based I–SNPs to contracts described in § 422.116(f)(3).

* * * * *

■ 31. Section 422.510 is amended by adding paragraph (e) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(e) If CMS makes a determination to terminate a MA organization's contract under § 422.510(a), CMS also imposes the intermediate sanctions at § 422.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction goes into effect 15 days after the termination notice is sent.

(2) The MA organization has a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction remains in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 32. Section 422.514 is amended by—

■ a. Revising paragraphs (d)(1) introductory text, (d)(1)(ii), (d)(2) introductory text, and (d)(2)(ii);.

■ b. In paragraph (e)(1)(i), removing the phrase ''Specialized MA Plan for Special Needs Individuals'' and adding in its place the phrase ''specialized MA plan for special needs individuals'';

■ c. In paragraph (e)(1)(iii), removing the phrase ''chapter; and'' and adding in its place ''chapter;'';

■ d. In paragraph (e)(1)(iv), removing the phrase ''of this section.'' and adding in its place ''of this section; and''; and

■ e. Adding paragraphs (e)(1)(v) and (h).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart for a MA plan that—

* * * * *

(ii) Projects enrollment in its bid submitted under § 422.254 in which enrollees entitled to medical assistance under a State plan under title XIX constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:—

(A) For plan year 2024, 80 percent.

(B) For plan year 2025, 70 percent.

(C) For plan year 2026 and subsequent years, 60 percent.

(2) Renew a contract under this subpart for an MA plan that—

* * * * *

(ii) 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, has

actual enrollment, as determined by CMS using the January enrollment of the current year in which enrollees who are entitled to medical assistance under a state plan under title XIX, constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For renewals for plan year 2024, 80 percent.

(B) For renewals for plan year 2025, 70 percent.

(C) For renewals for plan year 2026 and subsequent years, 60 percent.

(e) * * *

(1) * * *

(v) For transitions for plan year 2027 and subsequent years, is a dual eligible special needs plan as defined in § 422.2.

* * * * *

(h) *Rule on dual eligible special needs plans in relation to Medicaid managed care.*

(1) Beginning in 2027, where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2) that enrolls full-benefit dual eligible individuals as defined in § 423.772, during the effective dates and in the same service area (even if there is only partial overlap of the service areas) of that Medicaid MCO contract, the MA organization—

(i) May only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as permitted in paragraph (h)(3) of this section; and

(ii) Must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

(2) Beginning in 2030, such D–SNPs may only enroll (or continue to cover individuals enrolled in (or in the process of enrolling in) the Medicaid MCO, except that such D–SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d).

(3)(i) If a State Medicaid agency's contract(s) with the MA organization differentiates enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility or benefit design used in the State's Medicaid managed care program(s) (as defined in § 438.2), the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D–SNPs for full-benefit dual eligible individuals in the same service area in accordance with the group (or groups) eligible for D–SNPs based on provisions of the contract with the State Medicaid agency under § 422.107.

(ii) If the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the—

(A) HMO D–SNPs is subject to paragraph (h)(1) of this section, the PPO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

(B) PPO D–SNPs is subject to paragraph (h)(1) of this section, the HMO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

■ 33. Section 422.516 is amended by revising paragraphs (a) introductory text and (a)(2) to read as follows:

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the provider-patient relationship, information with respect to the following:

* * * * *

(2) The procedures related to and utilization of its services and items.

* * * * *

■ 34. 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 all of 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.

(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 has 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 an 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 does not consider subsequent requests for appeal.

(c) *Actions if an MA organization does not request an appeal.* (1) For MA organizations that are owed money by CMS, CMS remits 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 is 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 refers the debt owed to CMS to the Department of the 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 conducts 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 § 422.528(a), is issued to the MA organization, CMS no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there are no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 35. 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), 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 do all of the following:

(A) Specify the calculation 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.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does 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 (a)(2)(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 is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The CMS reconsideration official 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 is 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 (a)(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 (a)(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 reviews 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 does 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 is 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 communicates 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.

■ 35a. Section 422.530 is amended by adding paragraph (c)(4)(iii) to read as follows:

§ 422.530 Plan crosswalks.

(c) * * *

(4) * * *

(iii) For contract year 2027 and subsequent years, where one or more MA organizations that share a parent organization seek to consolidate D–SNPs in the same service area down to a single D–SNP under one MA–PD contract to comply with requirements at §§ 422.514(h) and 422.504(a)(20), CMS permits enrollees to be moved between different contracts.

* * * * *

■ 36. 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 as described in § 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 (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) 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 if applicable; and

(B) If the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 422.550(c) 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 paragraph (d)(1) of this section, submit the documentation required under § 422.550(c) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (d)(1)(ii) of this section within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, the existing contract is subject to termination in accordance with § 422.510(a)(4)(ix).

* * * * *

■ 37. Section 422.582 is amended by revising paragraph (b) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

(1) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * * *

■ 38. Section 422.584 is amended by revising paragraph (b) introductory text and adding paragraphs (b)(3) and (4) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(b) *Procedure and timeframe for filing a request.* A request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

* * * * *

(3) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * * *

■ 39. Section 422.626 is amended by revising paragraph (a)(2) and removing paragraph (a)(3) to read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) * * *

(2) If an enrollee makes an untimely request to an IRE, the IRE accepts the request and makes a determination as soon as possible, but the timeframe under paragraph (d)(5) of this section and the financial liability protection under paragraph (b) of this section do not apply.

* * * * *

■ 40. Section 422.633 is amended by revising paragraph (d)(1) to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(d) * * *

(1) *Timeframe for filing*—An enrollee has 60 calendar days after receipt of the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(i) The date of receipt of the adverse organization determination is presumed to be 5 calendar days after the date of the integrated organization determination notice, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the applicable integrated plan.

* * * * *

■ 41. 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) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) 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.

* * * * *

■ 42. Section 422.2267 is amended by—

■ a. Revising paragraphs (e)(31) and (34);

■ b. Adding paragraph (e)(42).

The revisions and additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(31) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).*

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian,

Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5 percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(31)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 422.2267(e)(31)(ii) to satisfy the MLI requirements set forth in paragraph (e)(31)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(31)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5 percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(34) *SSBCI disclaimer.* This is model content and must be used by MA organizations that offer CMS-approved SSBCI as specified in § 422.102(f). In the SSBCI disclaimer, MA organizations must include the information required in paragraphs (i) through (iii) of this section. MA organizations must—

(i) * * *

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the applicable MA plan(s), in accordance with the following requirements.

(A) The following applies when only one type of SSBCI is mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s).

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, and convey that there are other eligible conditions not listed.

(B) The following applies when multiple types of SSBCI are mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s), and if relevant, state that these conditions may not apply to all types of SSBCI mentioned.

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, for which one or more listed SSBCI is available, and convey that there are other eligible conditions not listed.

(iii) Convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in § 422.102(f)(1)(i)(A) and on the applicable MA plan's coverage criteria for a specific SSBCI required by § 422.102(f)(4).

(iv) Meet the following requirements for the SSBCI disclaimer in ads:

(A) For television, online, social media, radio, or other voice-based ads, either read the disclaimer at the same pace as, or display the disclaimer in the same font size as, the advertised phone number or other contact information.

(B) For outdoor advertising (as defined in § 422.2260), display the disclaimer in the same font size as the advertised phone number or other contact information.

(v) Include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI.

* * * * *

(42) *Mid-year supplemental benefits notice.* This is a model communications material through which plans must inform each enrollee of the availability of any item or service covered as a supplemental benefit that the enrollee has not begun to use by June 30 of the plan year.

(i) The notice must be sent on an annual basis, no earlier than June 30 of the plan year, and no later than July 31 of the plan year.

(ii) The notice must include the following content:

(A) *Mandatory supplemental benefits.* For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(B) *Optional supplemental benefits.* For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(C) *SSBCI.* For plans that include SSBCI—

(*1*) The MA organization must include an explanation of SSBCI available under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must include point-of-contact information for eligibility assessments, including providing point-of-contact information (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to

address any other questions the enrollee may have about the availability of SSBCI under their plan;

(*2*) When an enrollee has been determined eligible for SSBCI but has not used SSBCI, the MA organization must include a description of the unused SSBCI for which the enrollee is eligible, and must include a description of any limitations on the benefit; and

(*3*) The disclaimer specified at paragraph (e)(34) of this section.

(D) The information about all supplemental benefits listed in the notice must include all of the following:

(*1*) Scope of benefit.

(*2*) Applicable cost-sharing.

(*3*) Instructions on how to access the benefit.

(*4*) Any applicable network information.

(E) Supplemental benefits listed consistent with the format of the EOC.

(F) A customer service number, and required TTY number, to call for additional help.

■ 43. Section 422.2274 is amended by—

■ a. In paragraph (a), revising the definitions for ''Compensation'' and ''Fair market value'';

■ b. Revising paragraphs (c)(5) and (c)(13), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, (e)(1) and (e)(2); and

■ c. Adding paragraph (g)(4).

The revisions and addition read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in an MA plan or product, or for services conducted as a part of the relationship associated with the enrollment into an MA plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For contract year 2025, there will be a one-time increase of $100 to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA growth percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued under § 422.312.

* * * * *

(c) * * *

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

* * * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) For contract years through contract year 2024, MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, MA organizations are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, MA organizations may pay compensation at or below FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, MA plans may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

* * * * *

(e) * * *

(1) For contract years through contract year 2024, payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(g) * * *

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 44. 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.

■ 45. Section 423.4 is amended by adding the definitions of ''Authorized generic drug'', ''Biological product'', ''Biosimilar biological product'', ''Brand name biological product'', ''Interchangeable biological product'', ''MTM program'', ''Reference product'', and ''Unbranded biological product'' in alphabetical order 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).

Biosimilar biological product means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that, in accordance with section 351(i)(2) of the Public Health Service Act (42 U.S.C. 262(i)(2)), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

* * * * *

Brand name biological product means a product licensed under section 351(a) (42 U.S.C. 262(a)) or 351(k) (42 U.S.C. 262(k)) of the Public Health Service Act and marketed under a brand name.

* * * * *

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 meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)), which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

* * * * *

MTM program means a medication therapy management program described at § 423.153(d).

* * * * *

Reference 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.

* * * * *

■ 46. Section 423.32 is amended by adding paragraphs (h), (i), and (j) 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 the individual's enrollment in that plan if the individual cancels the election in the new plan within 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.

* * * * *

(j) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 47. 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; and

(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 (b)(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.

* * * * *

■ 48. Section 423.38 is amended by—

■ a. Revising paragraph (c)(4)(i), (c)(7), and (c)(23) introductory text;

■ b. Redesignating paragraphs (c)(23)(i) through (c)(23)(iii) and (c)(35), as paragraphs (c)(23)(ii) through (c)(23)(iv) and (c)(36), respectively; and
■ c. Adding new paragraphs (c)(23)(i) and (c)(35).

The revision and addition read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(4) * * *

(i) Except as provided in paragraph (ii) of this section, the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making a one-time-per month election into a PDP.

* * * * *

(7)(i) 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; or

(ii) The individual who, as a result of a change in permanent residence, has new Part D plan options available to them.

* * * * *

(23) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for an 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 is 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.

* * * * *

(35)(i) The individual is a full-benefit dual eligible individual (as defined in § 423.772) making a one-time-per month election into a fully integrated dual eligible special needs plan as defined in § 422.2 of this chapter, a highly integrated dual eligible special needs plan as defined in § 422.2 of this chapter, or an applicable integrated plan as defined in § 422.561 of this chapter.

(ii) The SEP is available only to facilitate aligned enrollment as defined in § 422.2 of this chapter.

* * * * *

■ 48a. Section 423.40 is amended by adding paragraph (f) to read as follows:

§ 423.40 Effective dates.

* * * * *

(f) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the Part D plan sponsor must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the Part D plan sponsor must attempt to contact the beneficiary and must document its attempts.

(2) If the Part D plan sponsor is unable to obtain the beneficiary's desired enrollment effective date, the Part D plan sponsor must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, the Part D plan sponsor must assign an election period that results in the earliest disenrollment.

■ 49. Section 423.44 is amended by—
■ a. Adding paragraph (b)(1)(iii);
■ b. Revising paragraphs (d)(1) introductory text, (d)(1)(iii)(A), (d)(1)(v), (d)(1)(vi) and (d)(2)(iii);
■ c. Redesignating paragraphs (d)(2)(iv) through (vii) as paragraphs (d)(2)(v) through (viii);
■ e. Adding new paragraph (d)(2)(iv);
■ f. Revising newly redesignated paragraph (d)(2)(v);
■ g. Revising paragraphs (d)(5)(i) and (d)(5)(ii); and
■ h. Adding paragraph (d)(9).

The 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 either of the following:

(A) 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.

(B) 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) *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 a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the individual does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(C) Shows good cause for failure to pay within the initial grace period.

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date.

(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 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—

(A) 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;

(B) May request from CMS the ability to decline future enrollment by the individual; and

(C) Must submit the following:

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section.

(*2*) Any documentation received by the individual to CMS.

(*3*) Dated copies of the notices required in paragraph (d)(2)(viii) of this section.

* * * * *

(viii) *Required notices.* The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) 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.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again.

(*2*) 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.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the PDP sponsor requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 423.44(c).

* * * * *

(5) * * *

(i) *Basis for disenrollment.* 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 10 calendar days of the 12th 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 U.S. 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.

* * * * *

■ 50. Section 423.100 is amended by revising paragraph (3) of the definition of ''Exempted beneficiary'' and adding the definitions of ''Affected enrollee'', ''Corresponding drug'', ''Immediate negative formulary change'', ''Maintenance change'', ''Negative formulary change'', ''Non-maintenance change'', and ''Other specified entities'' in alphabetical order to 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 product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

* * * * *

Exempted beneficiary means with respect to a drug management program, an enrollee who—

* * * * *

(3) Is being treated for cancer-related pain or

* * * * *

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 one of the following negative formulary changes with respect to a covered Part D drug:

(1) Making any negative formulary changes to a drug within 90 days of adding a corresponding drug to the same or a 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) Making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

(3) Removing a non-Part D drug.

(4) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.

(5) Removing a drug withdrawn from sale by the manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons if the Part D

sponsor chooses not to treat it as an immediate negative formulary change.

(6) Removing a drug based on long term shortage and market availability.

(7) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.

(8) Adding PA to help determine Part B versus Part D coverage.

* * * * *

Negative formulary change means one of the following changes with respect to a covered Part D drug:

(1) Removing a drug from a formulary.

(2) Moving a drug to a higher cost-sharing tier.

(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.

§ 423.104 [Amended]

■ 51. Section 423.104 is amended in paragraph (d)(2)(iv)(A)(6) by 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)''.

■ 52. Section 423.120 is amended by-—

■ a. Revising paragraph (b)(3)(i)(B);

■ b. Revising paragraphs (b)(5) and (6); and

■ c. Adding paragraphs (e) and (f).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(3) * * *

(i) * * *

(B) Not apply in cases of immediate changes as permitted under paragraph (e)(2) of this section.

* * * * *

(5) Notice of formulary changes. Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f).

(6) Changes to CMS-approved formularies. Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

* * * * *

(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 make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding 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 withdrawn from sale by their manufacturer or that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.

(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; about 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 all of 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 on the formulary in the same or a lower cost-sharing tier and the expected cost sharing for those drugs.

(v) For formulary changes other than those described in paragraph (e)(2)(ii) of this section, the means by which enrollees may obtain a coverage determination under § 423.566, including an exception to a coverage rule 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 providing—

(i) 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

(ii) 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.

* * * * *

■ 53. Section 423.128 is amended by revising paragraphs (d)(1)(v)(B), (d)(2)(iii), and (e)(6) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(1) * * *

(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).

* * * * *

■ 54. Section 423.129 is added to read as follows:

§ 423.129 Resolution of complaints in complaints tracking module.

(a) *Definitions.* For the purposes of this regulation, the following terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

Complaints Tracking Module is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaint*s. The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under § 423.564(f), if a complaint is also a grievance within the scope of § 423.564 and the requirements for an extension of the time to provide a response in § 423.564(e)(2) are met, the Part D sponsor may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 423.564 or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the Part D sponsor must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

§ 423.150 [Amended]

■ 55. Section 423.150 is amended in paragraph (a) by removing the phrase ''medication therapy management programs (MTMP)'' and adding in its place ''MTM programs''.

■ 56. Section 423.153 is amended by—

■ a. Revising the section heading;

■ b. Removing the paragraph heading from paragraph (d);;

■ 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 paragraph (d)(2)(i)(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).

■ k. In paragraph (f)(8)(i) introductory text, removing the phrase ''paragraph (f)(8)(ii)'' and adding in its place ''paragraphs (f)(8)(ii) and (iii)'';

■ l. Revising paragraph (f)(8)(i)(A);
■ m. Redesignating paragraph (f)(8)(ii) as paragraph (f)(8)(iii); and
■ n. Adding a new paragraph (f)(8)(ii).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) ***

(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) * * *

(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) of this section.

(*1*) For 2011, the MTM cost threshold is set at $3,000.

(*2*) For 2012 through 2024, the MTM cost threshold is set at $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(*3*) For 2025, the MTM cost threshold is set at the average annual cost of eight 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, 2025, 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).

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2025, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all Part D maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations, and may include all Part D drugs.

* * * * *

(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.

* * * * *

(f) * * *

(8) * * *

(i) * * *

(A) Within 3 days of the date the sponsor makes the relevant determination.

* * * * *

(ii) In the case of a beneficiary who is determined by a Part D sponsor to be exempt, the sponsor must provide the alternate second notice within 3 days of the date the sponsor makes the relevant determination, even if such determination is made less than 30 days from the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

§ 423.165 [Amended]

■ 57. Section 423.165 is amended in paragraph (b)(2) by removing the phrase ''MTMPs'' and adding the phrase ''MTM programs'' in its place.

■ 58. Section 423.184 is amended by—
■ a. Revising paragraph (d)(1)(v);
■ b. Reserving paragraph (g)(1)(ii); and
■ c. Adding paragraph (h)(3).

The revision and addition read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(g) * * *

(1) * * *

(ii) [Reserved]

* * * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), Part D sponsor may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 59. Section 423.186 is amended by—
■ a. Revising paragraph (e)(2);
■ b. Revising paragraph (f)(2)(i)(B); and
■ c. Adding paragraphs (f)(3)(viii)(A) and (B).

The revisions and addition read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(e) * * *

(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, a new or substantively updated measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined

across the surviving and consumed contracts in the consolidation.

(*2*) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(*3*) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(*4*) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

* * * * *

(3) * * *

(viii) * * *

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 60. Section 423.265 is amended by adding paragraph (b)(5) to read as follows:

§ 423.265 Submission of bids and related information.

(b) * * *

* * * * *

(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.

* * * * *

§ 423.293 [Amended]

■ 61. Section 423.293 is amended in paragraph (a)(4) by removing the phrase ''Medicare Advantage organization'' and adding in its place ''Part D sponsor''.

* * * * *

■ 62. 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;

(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.* (i) If the Part D sponsor does not issue the refund as required under this section within the timeframe specified at § 423.466(a), CMS reduces the premium the Part D sponsor is allowed to charge a Part D enrollee by the amounts incorrectly collected or otherwise due.

(ii) 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.

■ 63. Section 423.308 is amended by adding in the definition for ''Reopening'' in alphabetical order to read as follows:

§ 423.308 Definitions and terminology.

* * * * *

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).

* * * * *

■ 64. 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 notifies 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 or direct and indirect remuneration (DIR) for the reopening. The notification to sponsor(s) must include the following:

(1) The date by which PDE or DIR data must be accepted by CMS to be included in the reopening, which is at least 90 calendar days after the date of the notification.

(2) A statement indicating the Part D contracts or types of contracts that is included in the reopening.

(f) CMS announces when it has completed a reopening and provide the sponsor(s) with all of 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 is available to the sponsor.

(4) The date by which a sponsor must submit an appeal, in accordance with § 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 ''Notice of final settlement,'' as described at § 423.521(a), as of the date CMS announces the completion of the reopening in accordance with 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.

■ 65. Section 423.501 is amended by adding the definitions of ''Final settlement adjustment period'', ''Final settlement amount'', and ''Final settlement process'' in alphabetical order to read as follows:

§ 423.501 Definitions.

* * * * *

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.

Final settlement amount means 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, nonrenewed, 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 all of 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 of this chapter).

(2) Part D annual reconciliation (described in § 423.343).

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320).

(4) MLR remittances (described in §§ 422.2470 of this chapter and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS does all of the following:

(1) Calculates the final settlement amount.

(2) Issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor.

(3) Receives responses from the Part D sponsor requesting an appeal of the final settlement amount.

(5) 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 is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

■ 66. Section 423.503 is amended by—

■ a. Adding paragraph headings for paragraphs (a)(1) through (3) and adding paragraph (a)(4); and

■ b. Revising paragraphs (b)(1)(i)(A) and (C).

The addition and revisions read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(a) * * *

(1) *Information used to evaluate applications.* * * *

(2) *Issuing application determination.* * * *

(3) *Limitation on PDP contracts under a single parent organization* * * *

(4) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 423.503(c) 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.

* * * * *

(b) * * *
(1) * * *
(i) * * *
(A) Was under an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).
* * * * *
(C) Filed for or is currently in federal or state bankruptcy proceedings.
* * * * *

■ 67. Section 423.505 is amended by revising paragraph (b)(22) and adding paragraph (i)(6) to read as follows:

§ 423.505 Contract provisions.

* * * * *
(b) * * *
(22) As described in § 423.129, address and resolve complaints received by CMS against the Part D sponsor in the Complaints Tracking Module.
* * * * *
(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.
(iv) Contracting with or selection of prescription drug providers for inclusion in the Part D sponsor's network.

■ 68. 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 does not 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.
* * * * *

■ 69. 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 requires, 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 is not 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.
* * * * *

■ 69a. Section 423.509 is amended by adding paragraph (f) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *
(f) If CMS makes a determination to terminate a Part D sponsor's contract under § 423.509(a), CMS also imposes the intermediate sanctions at § 423.750(a)(1) and (3) in accordance with the following procedures:
(1) The sanction will go into effect 15 days after the termination notice is sent.
(2) The Part D sponsor will have a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.
(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.
(4) The sanction will remain in effect—
(i) Until the effective date of the termination; or
(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 69b. Section 423.514 is amended by revising paragraph (a) introductory text and paragraph (a)(2) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, information indicating the following—
* * * * *
(2) The procedures related to and utilization of its services and items.
* * * * *

■ 69c. Section 423.521 is added 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 for the contract that has been consolidated, nonrenewed, or terminated, which may be one of the following:
(i) An amount due to the Part D sponsor.
(ii) An amount due from the Part D sponsor.
(iii) $0 if nothing is due to or from the Part D sponsor.
(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount.
(3) Relevant CMS contact information.
(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 has 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 does 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 remits 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 is 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 refers the debt owed to CMS to the Department of the 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 conducts 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 § 423.521(a), is issued to the Part D sponsor, CMS—

(1) No longer applies retroactive payment adjustments to the terminated, consolidated or nonrenewed contract; and

(2) There are no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 69d. Section 423.522 is added 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 do all of the following:

(A) Specify the calculation with which the Part D sponsor disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does 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's 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 (a)(2)(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's 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 is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date.

(B) The CMS reconsideration official 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 is 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 (a)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(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.

(B) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews 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's calculation of the final settlement amount. CMS does 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.

(e) *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 is 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 communicates with the Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(f) *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.

■ 70. Section 423.530 is added 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 is not 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 the following:

(A) The current year's premium for the non-renewing PBP.

(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 does 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 in accordance with §§ 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 is not 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), for the region in which the PBP operates.

(d) *Procedures.* (1) A PDP sponsor must submit the following:

(i) All plan crosswalks described in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline.

(ii) 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.

(2) CMS verifies the requests and notifies a requesting PDP sponsor of the approval or denial after the crosswalk exception request deadline.

■ 71. 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 as described in § 423.509(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 423.750(a)(1) and (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) 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

(B) 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 paragraph (e)(1) of this section, submit the documentation required under § 423.551(d) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (e)(1)(i) or (e)(1)(ii) of this section, within 30 days of imposition of intermediate sanctions as outlined in paragraph (e)(1) of this section, the existing contract is subject to termination in accordance with § 423.509(a)(4)(ix).

* * * * *

■ 72. 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.

* * * * *

■ 73. Section 423.578 is amended by revising paragraph (d) to read as follows:

§ 423.578 Exceptions process.

* * * * *

(d) Notice regarding formulary changes. Whenever a Part D plan sponsor makes any negative formulary change, as defined in § 423.100, to its CMS-approved formulary, the Part D plan sponsor must provide notice in accordance with the requirements at § 423.120(b)(5) and (f).

■ 74. Section 423.582 is amended by revising paragraph (b) to read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or the at-risk determination under a drug management program in accordance with § 423.153(f).

(1) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

■ 75. Section 423.584 is amended by revising paragraph (b) introductory text and adding paragraph (b)(3) and (4) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(b) *Procedure and timeframe for filing a request.* A request for redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or at-risk determination notice.

* * * * *

(3) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

■ 76. Section 423.600 is amended by revising paragraph (a) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days after receipt of the written redetermination by the Part D plan sponsor.

(1) The date of receipt of the redetermination is presumed to be 5 calendar days after the date of the Part D plan sponsor's written redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the IRE specified in the Part D plan sponsor's written redetermination.

* * * * *

■ 77. Section 423.760 is amended by revising paragraph (b)(3) to read as follows:

§ 423.760 Definitions for calculating penalty amounts.

* * * * *

(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) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and

aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) 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.

* * * * *

■ 78. Section 423.2267 is amended by revising paragraph (e)(33) to read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(33) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).*

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(33)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in paragraph (e)(33)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(33)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

■ 79. Section 423.2274 is amended by—

■ a. Revising paragraph (i) of the definition of ''Compensation'' and the definition of ''Fair market value'' in paragraph (a);

■ b. Adding paragraph (c)(13);

■ c. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, (e)(1) and (e)(2);

■ d. Adding paragraph (g)(4).

The revisions and addition read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in a Part D plan or product, or for services conducted as a part of the relationship associated with the enrollment into a Part D plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. Beginning January 1, 2021, the national FMV is 81. In contract year 2025, there will be a one-time increase of $100 to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the produce of the current year FMV and Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued under § 422.312.

* * * * *

(c) * * *

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

* * * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) For contract years through contract year 2024, Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, Part D sponsors are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, Part D sponsors may pay compensation at or below FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, Part D sponsors may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

* * * * *

(e) * * *

(1) For contract years through contract year 2024, payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(g) * * *

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into a Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the information and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 80. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 80a. Section 460.12 is amended by revising paragraph (a) 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 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 in accordance with 42 CFR part 423, subpart K.

■ 81. Section 460.18 is amended by adding paragraphs (c) and (d) to read as follows:

§ 460.18 CMS evaluation of applications.

* * * * *

(c) *Use of information from a current or prior PACE program agreement.* (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 following conditions apply with respect to the applicant during the applicable 12-month review period:

(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. Corrective action requests issued under § 460.194 are not included in the point calculations.

(*ii*) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(*iii*) Each notice of non-compliance 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.

(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.

* * * * *

■ 81. 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 Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining non-compliance, CMS may determine that a 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 non-compliance, 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 non-compliance was self-reported.

(6) 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.

(c) CMS may take one of three types of compliance actions based on the nature of the non-compliance.

(1) *Notice of non-compliance.* A notice of non-compliance 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 non-compliance 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 non-compliance 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 non-compliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its non-compliance, or must implement a detailed plan to correct the underlying causes of the non-compliance.

■ 82. Section 460.20 is amended by revising paragraph (c) to read 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) is withdrawn by CMS and the applicant is notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

■ 83. 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.

(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; and

(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 do both of the following:

(*1*) Assess whether staff have been exposed to or have any symptoms of the following diseases:

(*i*) COVID–19.

(*ii*) Diphtheria.

(*iii*) Influenza.

(*iv*) Measles.

(*v*) Meningitis.

(*vi*) Meningococcal Disease.

(*vii*) Mumps.

(*viii*) Pertussis.

(*ix*) Pneumococcal Disease.

(*x*) Rubella.

(*xi*) Streptococcal Infection.

(*xii*) Varicella Zoster Virus.

(*xiii*) 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.

* * * * *

■ 84. 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 follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases before engaging

in direct participant contact as required under § 460.64(a)(5).

(5) Have all immunizations up to date before engaging in direct participant contact.

* * * * *

■ 85. Section 460.98 is amended by:
■ a. Removing paragraph (b)(4);
■ b. Redesignating paragraphs (b)(5) and (c) through (e) as paragraphs (b)(4) and (d) through (f), respectively; and
■ c. 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.

■ 87. 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 the following:

(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 as expeditiously as the participant's health condition requires, but no later than 48 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 7 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).

■ 88. 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.

■ 87. Section 460.106 is revised to read as follows:

§ 460.106 Plan of care.

(a) *Definition and basic requirements*—(1) *Definition.* 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.

(2) *Basic requirements.* (i) 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.

(ii) Each plan of care must do all of the following:

(A) Take into consideration the most current assessment findings.

(B) 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 from the date the latest plan of care was finalized 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.

(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.

(xiii) Communication, including any identified language barriers.

(2)(i) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs.

(ii) It 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.* The team must continuously do all of the following:

(1) 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) 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 or the participant's caregiver or both 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 do all of the following:

(1) Establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record.

(2) Ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

■ 88. 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;

■ f. Adding paragraph (c)(5);

■ g. Revising paragraph (e)(1);

■ h. Redesignating paragraphs (e)(2) through (6) as (e)(3) through (7);

■ i. Adding new paragraph (e)(2);

■ j. Revising the paragraph heading for paragraphs (g) introductory text and revise paragraph (g)(2); and

■ k. Adding paragraph (g)(3).

The additions and revisions 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 all of the following:

(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.

(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) is provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that are impacted and provide a detailed explanation of how the services will be impacted if the participant 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.
(ii) 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 all of the following:

(i) Have all treatment options fully explained.

(ii) Refuse any and all care and services.

(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.

■ 89. Section 460.119 is added to read as follows:

§ 460.119 Resolution of complaints in the complaints tracking module.

The PACE organization must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the PACE organization within the required timeframes. References to the MA organization or MA plan in those regulations must be read as references to the PACE organization. Nothing in this section should be construed to affect the PACE organization's obligation to resolve grievances as described in § 460.120, service determinations as described in § 460.121, or appeals as described in § 460.122.

■ 90. Section 460.120 is revised to read as follows:

§ 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 all of the following:

(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 (j) 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.

(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.* The PACE organization must do all of the following:

(1) 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) 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) *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 (h)(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) A summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation.

(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.

(i) 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.

(ii) 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 (h)(1) through (3) of this section.

(i) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(j) *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.

(k) *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 (j) of this section, must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(l) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (k) of this section for purposes of its internal quality improvement program.

■ 91. Section 460.121 is amended by revising paragraph (b)(2) to read as follows:

§ 460.121 Service determination process.

* * * * *

(b) * * *

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. For all requests identified in this section, the interdisciplinary team must—

(i) Document the request; and

(ii) Discuss the request during the care planning meeting, and either:

(A) Approve the requested service and incorporate it into the participant's initial plan of care, or

(B) Document their rationale for not approving the service in the initial plan of care.

* * * * *

■ 92. Section 460.194 is amended by revising paragraph (b) to read as follows:

§ 460.194 Corrective action.

* * * * *

(b) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

* * * * *

■ 93. Section 460.198 is added 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.

* * * * *

§ 460.202 [Amended]

■ 94. Section 460.202(b) is amended by removing the last sentence.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–07105 Filed 4–4–24; 5:10 pm]

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Part III

Department of Housing and Urban Development

24 CFR Parts 50, 55, 58, et al.
Floodplain Management and Protection of Wetlands; Minimum Property Standards for Flood Hazard Exposure; Building to the Federal Flood Risk Management Standard; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 50, 55, 58, and 200

[Docket No. FR–6272–F–02]

RIN 2506–AC54

Floodplain Management and Protection of Wetlands; Minimum Property Standards for Flood Hazard Exposure; Building to the Federal Flood Risk Management Standard

AGENCY: Office of the Secretary, U.S. Department of Housing and Urban Development (HUD).

ACTION: Final rule.

SUMMARY: This final rule revises HUD's regulations governing floodplain management and the protection of wetlands to implement the Federal Flood Risk Management Standard (FFRMS) in accordance with the Executive Order titled ''Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input.'' These revisions to HUD's regulations will improve the resilience of HUD-assisted or financed projects to the effects of climate change and natural disasters and provide for greater flexibility in the use of HUD assistance in floodways under certain circumstances. Among other revisions, this rule provides a process for determining the extent of the FFRMS floodplain, with a preference for a climate-informed science approach (CISA) to making this determination. The rule also revises HUD's floodplain and wetland regulations to streamline, improve overall clarity, and modernize standards. Also, this rule revises HUD's Minimum Property Standards for one-to-four-unit housing under HUD's mortgage insurance and low-rent public housing programs to require that the lowest floor in newly constructed structures located within the 1-percent-annual-chance (100-year) floodplain be built at least 2 feet above the base flood elevation (BFE) as determined by best available information. The rule also revises a categorical exclusion when HUD performs environmental reviews and updates various HUD environmental regulations to permit online posting of public notices.

DATES:

Effective Date: May 23, 2024.

Compliance Date: Compliance with this final rule is required no later than June 24, 2024, except: compliance with this final rule's amendments to 24 CFR part 200 is required for new construction where building permit applications are submitted on or after January 1, 2025; and compliance with this final rule's amendments to 24 CFR part 55 is required no later than January 1, 2025 for the following programs: (1) Programs subject to chapter 9 of the Federal Housing Administration's (FHA) Multifamily Accelerated Processing (MAP) Guide (4430.G): Multifamily FHA, Section 202 and 811 capital advance grants, transfers under Section 8(bb) of the United States Housing Act and Section 209 of HUD's annual appropriations (or subsequent provisions), Section 8 Renewals with Capital Repairs, Rental Assistance Demonstration (RAD) conversions to Project-Based Rental Assistance (PBRA), and the Green and Resilient Retrofit Program; and (2) The other mortgage insurance programs subject to part 55: FHA Healthcare and FHA Risk Share.

FOR FURTHER INFORMATION CONTACT: Kristin L. Fontenot, Director, Office of Environment and Energy, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7282, Washington, DC 20410–8000. For inquiry by phone or email, contact Lauren Hayes Knutson, Director, Environmental Planning Division, Office of Environment and Energy, Office of Community Planning and Development, at 202–402–4270 (this is not a toll-free number) or email to: *EnvironmentalPlanningDivision@hud.gov.* For questions regarding the Minimum Property Standards, contact Julie Shaffer, Associate Deputy Assistant Secretary, Office of Single Family Housing, 215–861–7216. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 24, 2023, HUD published the ''Floodplain Management and Protection of Wetlands; Minimum Property Standards for Flood Hazard Exposure; Building to the Federal Flood Risk Management Standard'' proposed rule (the ''proposed rule'').[1] In the proposed rule, HUD explained that increased and increasing frequency of flooding and weather and climate disasters make it necessary for HUD to ensure it approves Federal investments wisely to minimize losses, particularly following repeated flooding events. The revisions to HUD's regulations implemented through this final rule will improve the resilience of HUD-assisted or financed projects to the effects of climate change and natural disasters and provide for greater flexibility in the use of HUD assistance in floodways under certain circumstances.

HUD has broad general rulemaking authority under 42 U.S.C. 3535 to ''make such rules and regulations as may be necessary to carry out [the Secretary's] functions, powers and duties'' in order to implement its statutory mission, which is to provide assistance for housing to promote ''the general welfare and security of the Nation and the health and living standards of [its] people.'' [2] Under the National Housing Act, HUD has discretion to set terms upon which it will insure mortgages. 12 U.S.C. 1701 *et seq.* HUD also has authority and responsibility under the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*):

- to use all practicable means;
- to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may:
  - fulfill the responsibilities of each generation as trustee of the environment for succeeding generations;
  - assure for all Americans safe, healthful, productive, and esthetically and culturally pleasing surroundings;
  - attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.

42 U.S.C. 4331(b).

NEPA also requires all Federal agencies to ''utilize a systematic, interdisciplinary approach which will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision making which may have an impact on man's environment.'' 42 U.S.C. 4332(2)(A). Each year, HUD provides States, local governments, and housing providers with billions of dollars in Federal financial assistance, appropriated and authorized by Congress. By taking the actions it does in this final rule, HUD protects Federal investments, preserves the environment for future generations, and promotes the health, safety, and general welfare of individuals. As described in the

[1] 88 FR 17755. On May 11, 2023, HUD extended the original 60-day comment period provided in the proposed rule by an additional 14 days. *See* 88 FR 30267.

[2] 42 U.S.C. 3531.

proposed rule, in response to the threats that increasing flood risks pose to life and taxpayer funded property, on January 30, 2015, President Obama signed Executive Order (E.O.) 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input.[3] E.O. 13690 amended E.O. 11988, Floodplain Management, which was originally issued in furtherance of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001 *et seq.*); the Flood Disaster Protection Act of 1973, as amended (Pub. L. 93–234, 87 Stat. 975); and NEPA (42 U.S.C. 4321 *et seq.*).

Significantly for the purposes of this rulemaking, E.O. 13690 revised section 6(c) of E.O. 11988 to provide new approaches to establish the floodplain. E.O. 13690 provided, however, that prior to any actions implementing E.O. 13690, additional input from stakeholders be solicited and considered. Consistent with this direction, the Federal Emergency Management Agency (FEMA), as Chair of the Mitigation Framework Leadership Group (MitFLG),[4] published a notice in the **Federal Register** seeking public comment on the proposed ''Revised Guidelines for Implementing Executive Order 11988, Floodplain Management'' to provide guidance to agencies on the implementation of E.O. 13690 and 11988.[5] In addition, MitFLG held nine public listening sessions across the country that were attended by over 700 participants from State and local governments and other stakeholder organizations to discuss the Revised Guidelines for Implementing Executive Order 11988, Floodplain Management.[6] MitFLG considered stakeholder input and provided recommendations to the U.S. Water Resources Council (WRC).[7]

On October 8, 2015, the WRC issued the updated ''Guidelines for Implementing Executive Order 11988, Floodplain Management, and Executive Order 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input'' (the ''Guidelines'').[8] Although the Guidelines describe various approaches for determining the higher vertical flood elevation and corresponding horizontal floodplain for federally funded projects, the Guidelines indicate that it is not meant to be an elevation standard but rather a resilience standard. Further, the Guidelines provide that all future actions where Federal funds are used for new construction, substantial improvement,[9] or to address substantial damage [10] meet the level of resilience established by the Guidelines. In implementing the Guidelines and establishing the FFRMS, Federal agencies were to select among the following three approaches for establishing the flood elevation and hazard area in siting, design, and construction:

- *Climate-Informed Science Approach (CISA):* The elevation and flood hazard area that result from using a climate-informed science approach that uses the best-available, actionable, hydrologic and hydraulic data;
- *Freeboard* [11] *Value Approach (FVA):* The elevation and flood hazard area that result from using the freeboard value reached by adding an additional 2 feet to the base flood elevation (the 100-year, or 1-percent-annual-chance flood elevation) for non-critical actions and by adding an additional 3 feet to the base flood elevation for critical actions, or
- *0.2-Percent-Annual-Chance (500-Year) Flood Approach:* The elevation and flood hazard area that result from using the 0.2-percent-annual-chance flood approach (500-year flood elevation).

The FVA and 0.2-percent-annual-chance flood approach result in higher elevations than the base flood elevation with correspondingly larger horizontal floodplain areas. CISA will generally have a similar result, with the exception that agencies using CISA may find the resulting elevation to be equal to or lower than the current elevation in some areas due to the nature of the specific climate change processes and physical factors affecting flood risk at the project site. However, as a matter of policy established in the Guidelines, CISA should only be used if the resulting flood elevation is at least equal to or higher, depending on the criticality of the action, than current base flood elevation.

In response to comments received on the Guidelines, MitFLG included an appendix that explained CISA. Appendix H of the Guidelines [12] explains that CISA treats the future as potentially non-stationary; considers local conditions as well as global change; accommodates other factors beyond those that are climate-related; and assists in bounding the decision space by considering plausible future conditions appropriate to a given decision. CISA uses existing sound science and engineering methods as have historically been used to implement E.O. 11988 but supplemented with best available

[3] 80 FR 6425 (Feb. 2, 2015). E.O. 13690 was revoked by E.O. 13807, Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects (Aug. 15, 2017); however, E.O. 13690 was reinstated by E.O. 14030, Climate-Related Financial Risk (May 20, 2021), published at 86 FR 27967.

[4] MitFLG is a senior level group formed in 2013 to coordinate mitigation efforts across the Federal Government and to assess the effectiveness of mitigation capabilities as they are developed and deployed across the Nation. The MitFLG includes relevant local, State, Tribal, and Federal organizations. More information about MitFLG can be found at *https://www.fema.gov/emergency-managers/national-preparedness/frameworks/mitigation/mitflg.*

[5] 80 FR 6530 (Feb. 5, 2015). The ''Revised Guidelines for Implementing Executive Order 11988, Floodplain Management'' is included as a supporting document with the docket associated with 80 FR 6530.

[6] Specific information on the listening sessions can be found in the notices on the docket at *https://www.regulations.gov/docket/FEMA-2015-0006/document?documentTypes=Notice.* Transcripts of those sessions are available on the docket at *https://www.regulations.gov/docket/FEMA-2015-0006/document?documentTypes=Supporting%20%26%20Related%20Material.*

[7] The WRC is a statutory body tasked to maintain a continuing study and prepare an assessment of the adequacy of supplies of water necessary to meet the water requirements in each water resource region in the United States and the national interest therein. 42 U.S.C. 1962a. The WRC is a means for the coordination of the water and related land resources policies and programs of several Federal agencies. The WRC is composed of the Secretary of the Interior, the Secretary of Agriculture, the Secretary of the Army, the Secretary of Commerce, the Secretary of Housing and Urban Development, the Secretary of Transportation, the Administrator of the Environmental Protection Agency, and the Secretary of Energy.

[8] The Guidelines are available at *https://www.fema.gov/sites/default/files/documents/fema_implementing-guidelines-EO11988-13690_10082015.pdf.* HUD notes that the WRC is not currently active.

[9] HUD defines substantial improvement in 24 CFR 55.2(b). This final rule does not substantively change this definition except by moving it from its current location in § 55.2(b)(10) to § 55.2(b)(12) to reflect other changes to that section and by clarifying that the term ''structure'' includes a manufactured housing unit.

[10] Substantial damage is defined in FEMA regulations at 44 CFR 59.1 as ''damage of any origin sustained by a structure whereby the cost of restoring the structure to its before damaged condition would equal or exceed 50 percent of the market value of the structure before the damage occurred.'' For more information on substantial improvement and substantial damage, *see* FEMA, Substantial Improvement/Substantial Damage Desk Reference FEMA P–758 (May 2010), available at *https://www.fema.gov/sites/default/files/2020-08/fema_p_758_complete_r3_0.pdf.*

[11] Freeboard is defined by FEMA as ''a factor of safety usually expressed in feet above a flood level for purposes of floodplain management. 'Freeboard' tends to compensate for the many unknown factors that could contribute to flood heights greater than the height calculated for a selected size flood and floodway conditions, such as wave action, bridge openings, and the hydrological effect of urbanization of the watershed.'' 44 CFR 59.1. *See also* FEMA, National Flood Insurance Program Terminology Index, available at *http://www.fema.gov/freeboard.*

[12] The appendices to the Guidelines are available at *https://www.fema.gov/sites/default/files/documents/fema_IGA-appendices-a-h_10082015.pdf.*

climate-related scientific information when appropriate. CISA is consistent with the climate science and related information found in the latest National Climate Assessment report or other best-available, actionable science. CISA combines information from different disciplines (like atmospheric sciences, coastal sciences, oceanographic sciences) in addition to traditional science and engineering approaches. CISA should include impacts from projected land cover and land use changes, long-term coastal and/or riverine erosion, and vertical land movement expected over the lifecycle of the action.

As described in the Guidelines, CISA relies on best available and actionable science. Best available means data and science that is transparent, technically credible, usable, legitimate, and flexible. Actionable science consists of theories, data, analyses, models, projects, scenarios, and tools that are relevant to the decision under consideration; reliable in terms of its scientific or engineering basis and appropriate level of peer review; understandable to those making the decision; supportive of decisions across wide spatial, temporal, and organization ranges; and co-produced by scientists, practitioners, and decision-makers. Appendix H indicates that different approaches are appropriate for coastal and riverine flooding because the directional change of local sea level plus storm surge is generally known for coastal flood risk but, for riverine, it is difficult to determine the direction of changes in precipitation and resulting flood elevations. As a result, the MitFLG recommended that coastal flood risks agencies take into account mean sea level rise scenarios that are adjusted to reflect local conditions to identify CISA. The MitFLG and Appendix H to the Guidelines do not provide a similar hydrologic standard for CISA for riverine flood risks because of the limitations on best-available and actionable science.

In 2023, Federal agencies participating in the White House Flood Resilience Interagency Working Group [13] reviewed the science behind CISA and concluded that incorporating the latest projections of sea level rise in evaluation of future coastal flood risk continues to be best practice and actionable science, whereas the science surrounding the climate change impacts to precipitation and inland flooding is not mature enough to establish one CISA standard for riverine flooding.[14] In August 2023, the White House Flood Resilience Interagency Working Group released a job aid to assist agencies with their responsibility to identify the floodplain using the three approaches.[15]

E.O. 11988 directs Federal agencies to avoid, to the extent possible, the long- and short-term adverse impacts associated with the occupancy and modification of floodplains and to avoid direct and indirect support of floodplain development wherever there is a practicable alternative. Floodplains are found both in coastal flood areas, where rising tides and storm surge are often responsible for flooding, and in riverine flood areas where moving water bodies may overrun their banks due to heavy rains or snow melt. E.O. 11988 directs each agency to evaluate the potential effects of any actions it may take in a floodplain; to ensure that agency planning programs and budget requests reflect consideration of flood hazards and floodplain management; and to identify the floodplain area.

E.O. 11988, as amended, requires agencies to take a scientific approach to determine if a proposed action is in or affects a floodplain. The result of this analysis is often most easily conveyed via a map, making floodplain maps ubiquitous with the process of identifying the floodplain, though, in process, they are separate. The identification of the floodplain is the analysis the agencies have been tasked with carrying out under E.O. 11988 and maps are the visual representation of that analysis. Because flood risk can change over time, FEMA and the National Flood Insurance Program (NFIP) program continually revise Flood Insurance Rate Maps (FIRMs), advisory base flood elevations and preliminary floodplain maps and studies to incorporate new information and reflect the current understanding of flood risk. E.O. 13690 amended E.O. 11988 to direct agencies to update the floodplain using one (or a combination) of the three approaches listed above, which are incorporated in the FFRMS.

Communities across the Nation have proactively strengthened their local floodplain management codes and standards to ensure that buildings and infrastructure are resilient to flood risk. By implementing the FFRMS, HUD's standards will better align with these actions and better protect against future flood risk, considering climate informed science, where available. At the same time, HUD recognizes that the need to make structures resilient also requires a flexible approach to adapt to the needs of the Federal agency, local community, and the circumstances surrounding each project or action.

II. This Final Rule

In its 2021 Climate Action Plan,[16] HUD committed to completing rulemaking to update 24 CFR part 55 and implement FFRMS as a key component of HUD's plan to increase climate resilience and climate justice across the Department, noting that underserved communities are disproportionately impacted by climate change.[17] Development of equitable strategies to protect low- to moderate-income persons and businesses serving communities disproportionately impacted by climate change is at the core of HUD's mission to create strong, sustainable, inclusive communities. This final rule will improve the resilience of HUD-assisted or financed projects to the effects of climate change and natural disasters and provide for greater flexibility in the use of HUD assistance in floodways under certain circumstances.

HUD notes that affordable housing is increasingly at risk from both extreme weather events and sea level rise, with coastal communities especially at risk. Recent peer-reviewed analysis and mapping by independent research organization Climate Central projects that the number of affordable housing units at risk from flooding in coastal areas will triple by 2050,[18] and a 2019 report from the Denali Commission found that 144 Native Alaskan Villages face infrastructure damage from erosion, flooding, and permafrost thaw.[19]

[13] More information about the White House Flood Resilience Interagency Working Group can be found at *https://www.whitehouse.gov/ceq/news-updates/2021/08/27/readout-of-the-first-white-house-flood-resilience-interagency-working-group-meeting-on-implementation-of-the-federal-flood-risk-management-standard/.*

[14] *See* Federal Flood Risk Management Standard Climate-Informed Science Approach (CISA) State of the Science Report (March 2023), *https://www.whitehouse.gov/wp-content/uploads/2023/03/Federal-Flood-Risk-Management-Standard-Climate-Informed-Science-Approach-CISA-State-of-the-Science-Report.pdf.*

[15] *See* FFRMS Floodplain Determination Job Aid (August 2023), *https://www.fema.gov/sites/default/files/documents/fema_ffrms-floodplain-determination-job-aid.pdf.*

[16] U.S. Department of Housing and Urban Development, Climate Action Plan (Nov. 2021), available at *https://www.hud.gov/climate.*

[17] *See also* Marino, E.K., K. Maxwell, E. Eisenhauer, A. Zycherman, C. Callison, E. Fussell, M.D. Hendricks, F.H. Jacobs, A. Jerolleman, A.K. Jorgenson, E.M. Markowitz, S.T. Marquart-Pyatt, M. Schutten, R.L. Shwom, and K. Whyte, 2023: Ch. 20. Social systems and justice. In: *Fifth National Climate Assessment.* Crimmins, A.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, B.C. Stewart, and T.K. Maycock, Eds. U.S. Global Change Research Program, Washington, DC, USA, available at *https://doi.org/10.7930/NCA5.2023.CH20.*

[18] Maya K. Buchanan et al. (2020). Environ. Res. Lett., 15, 124020.

[19] Alaska Division of Geological & Geophysical Surveys. February 23, 2021. *Alaska's*

HUD's experience in the wake of flood disasters is that unless structures in flood-prone areas are properly designed, constructed, and elevated, they may not withstand future severe flooding events. This risk is exacerbated by climate change and projected increases in hurricane rainfall and intensity as well as other precipitation throughout most of the United States. This final rule provides for a more forward-looking approach to floodplain management, which bases decisions not just on past flooding but on how flood risk is anticipated to grow and change over the anticipated life of a project.

This final rule expands the floodplain of concern from the 1-percent-annual-chance floodplain to the FFRMS floodplain, designated based on projected future flood risk, to ensure that HUD projects are designed with a more complete picture of a proposed project site's flood risk over time. Flood risk projection based on current climate science can help HUD meet the objectives of E.O. 11988, including avoidance of floodplain impacts and minimization of such impacts where there is no practicable alternative to locating a HUD-assisted activity in proximity to flood sources. Adequate elevation of structures is a key minimization strategy, together with complementary natural ecosystem processes and nature-based approaches, to promote the preservation of beneficial floodplain functions.

As recognized by MitFLG and directed by the FFRMS and E.O. 13690, requiring structures located within the expanded FFRMS floodplain to be elevated or floodproofed to an additional elevation above the base flood elevation will increase resiliency and reduce loss of life, property damage, and other economic loss, and can also benefit property owners by reducing flood insurance rates. These higher standards provide an extra buffer above the base flood elevation based on the best available information to improve the long-term resilience of communities. Additionally, higher standards help account for increased flood risk associated with projected sea level rise, increased rainfall, and other climate risks, which are not considered in current FEMA maps and flood insurance costs. As stated in the report ''Global and Regional Sea Level Rise Scenarios for the United States'' (February 2022) by the U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA),[20] scientists are confident that global sea level will rise by between about 1 and as much as 6.56 feet by the year 2100.[21] The higher standards required, in some cases, by this final rule allow HUD to do more to address these increasing risks.

Choosing alternative sites outside the FFRMS floodplain and requiring additional elevation above the base flood elevation may also lead to a net reduction of expected housing costs over time. HUD's mission is to create strong, sustainable, inclusive communities and quality affordable homes for all. Flood insurance is a key financial tool to manage potential rebuilding costs and can make homes in risky areas more expensive due to their greater flood risk. By elevating additional feet above the base flood elevation, homeowners may benefit from flood insurance premium reductions that will increase long-term affordability.

Through this final rule, HUD is prioritizing using CISA in defining the floodplain because it provides a forward-looking assessment of flood risk based on likely or potential climate change scenarios, regional climate factors, and an advanced scientific understanding of these effects. Therefore, in this final rule, HUD will require the use of CISA, where data is available and actionable, to establish the required level of flood resilience for floodplain management decision making, elevation of structures, and floodproofing. In areas where CISA data is not currently available and actionable to define the FFRMS floodplain, as described in this final rule, HUD will typically require that the FFRMS floodplain to be based on the FEMA-mapped 0.2-percent-annual-chance floodplain or a freeboard height above the FEMA-mapped 1-percent-annual-chance floodplain, as further described in the subsection that follows. As CISA data availability improves over time and over a greater area, HUD expects the use of CISA to increase.

Beyond implementing the FFRMS floodplain and elevation requirements, this final rule implements broader changes to modernize and improve 24 CFR part 55 in accordance with the Department's climate adaptation, environmental justice, and equity priorities. These revisions explicitly recognize HUD's responsibility to consider the environmental justice impact of the Department's actions within the floodplain management and decision making process. To meet HUD's affordable housing and community development mission more effectively and efficiently, this final rule also streamlines decision making for activities that mitigate flood risk, avoid wetland losses, or provide co-benefits that directly contribute to HUD's efforts to reduce climate impacts. This final rule also strengthens HUD's commitment to use nature-based floodplain management approaches, where practicable, by identifying specific strategies and practices that have proven effective in increasing flood resilience and environmental quality.

HUD notes that adherence to the requirements in this final rule does not modify any party's responsibilities or obligations under any other Federal laws, including statutes and regulations administered by other Federal agencies.

A. Federal Flood Risk Management Standard (FFRMS) Floodplain

To implement the framework described in this rule, this final rule defines the FFRMS floodplain in a new 24 CFR 55.7. This new section establishes a three-tiered approach to define the FFRMS floodplain, depending on the data available in the project area.

1. *Climate Informed Science Approach (CISA):* The FFRMS floodplain is defined as areas designated as having an elevated flood risk during the anticipated life of the project based on CISA. CISA will generally use the same methodology for both critical and non-critical actions; however, the selection of climate change scenarios used for future projections should account for the lower tolerance of risk based on the action's criticality. Where

Environmentally Threatened Communities. ArcGIS, *https://storymaps.arcgis.com/stories/2a0d221e55ca48dd8092427b50a98804* (*interpreting* University of Alaska Fairbanks Institute of Northern Engineering et al., *Statewide Threat Assessment: Identification of Threats from Erosion, Flooding, and Thawing Permafrost in Remote Alaska Communities—Report Prepared for the Denali Commission*), November 2019, available at *https://www.denali.gov/wp-content/uploads/2019/11/Statewide-Threat-Assessment-Final-Report-20-November-2019.pdf.*

[20] Sweet, W.V., B.D. Hamlington, R.E. Kopp, C.P. Weaver, P.L. Barnard, D. Bekaert, W. Brooks, M. Craghan, G. Dusek, T. Frederikse, G. Garner, A.S. Genz, J.P. Krasting, E. Larour, D. Marcy, J.J. Marra, J. Obeysekera, M. Osler, M. Pendleton, D. Roman, L. Schmied, W. Veatch, K.D. White, and C. Zuzak, 2022: Global and Regional Sea Level Rise Scenarios for the United States: Updated Mean Projections and Extreme Water Level Probabilities Along U.S. Coastlines. NOAA Technical Report NOS 01. National Oceanic and Atmospheric Administration, National Ocean Service, Silver Spring, MD, 111 pp., *https://oceanservice.noaa.gov/hazards/sealevelrise/sealevelrise-tech-report.html.*

[21] *Id. See also* NOAA Climate Change Program Office, United States Global Change Research Program, U.S. Climate Resilience Toolkit, available at *https://toolkit.climate.gov/topics/coastal/sea-level-rise.*

part 55 applies,[22] CISA is the required approach to define the FFRMS floodplain if data is available and actionable. When preparing an Environmental Impact Statement (EIS), an analysis of sea level rise and other climate impacts utilizing CISA and other climate risk tools will be required regardless of whether pre-existing data is available for reference. Because EIS level projects have such a high potential for adverse impacts, HUD believes climate informed science is necessary to fully understand the potential environmental concerns, where available and actionable data exists or can be generated in accordance with 42 U.S.C. 4336(b)(3).

2. *0.2-Percent-Annual-Chance Flood Approach (0.2 PFA):* For non-critical actions, where CISA data or other types of CISA analysis is not available or actionable, but FEMA has defined the 0.2-percent-annual-chance floodplain, the FFRMS floodplain is defined as those areas that FEMA has designated as within the 0.2-percent-annual-chance floodplain. For critical actions where CISA data is not available nor actionable, the FFRMS floodplain is defined as either the area within the 0.2-percent-annual-chance floodplain or the area that results from adding an additional three feet to the base flood elevation, whichever results in the larger floodplain and higher elevation. For any action, newly constructed or substantially improved structures within this definition of the FFRMS floodplain are required to be elevated to or above the FFRMS floodplain.

3. *Freeboard Value Approach (FVA):* For non-critical actions, if CISA data is not available or actionable and the FEMA 0.2-percent-annual-chance floodplain is not defined, the FFRMS floodplain is defined as those areas, including the horizontal extent, that result from adding an additional two feet to the base flood elevation as established by the effective FEMA FIRM or Flood Insurance Study (FIS). If available, a FEMA-provided interim or preliminary FIRM, FIS, or advisory base flood elevation, whether regulatory or informational in nature, may also be used; however, an interim or preliminary FEMA analysis map may not be used if the mapped base flood elevation is lower than the current FIRM or FIS. For critical actions where CISA data is not available or actionable and where the 0.2-percent-annual-chance floodplain elevation is not defined, the FFRMS floodplain is defined as those areas, including the horizontal extent, that result from adding an additional three feet to the base flood elevation.

If CISA data is not available or actionable and FEMA FIRMs, FIS, preliminary maps, and advisory base flood elevations are unavailable or insufficiently detailed to determine base flood elevation, other Federal, State, local, or Tribal data may be used as ''best available information'' to define the 1-percent-annual-chance floodplain.

B. Climate Informed Science Approach—Availability and Actionability of Data

As described throughout this final rule, CISA is the preferred approach to define the FFRMS floodplain. In § 55.7, HUD requires that the FFRMS floodplain be defined using CISA where data is available and actionable.

As described in § 55.7, HUD considers CISA data to be available and actionable for a particular project where: (1) the data is included in a tool, resource, or other process developed or identified by a Federal agency or agencies to define the floodplain using CISA, and (2) HUD has adopted the particular tool, resource, or other process through a **Federal Register** notice for comment. As a matter of policy, HUD has decided to publish a **Federal Register** notice for comment prior to the use of a particular tool, resource, or other process under § 55.7.

Regardless of whether HUD has adopted a particular tool, resource, or other process to define the floodplain using CISA, this final rule at § 55.7(f) permits HUD or a responsible entity to voluntarily define the FFRMS floodplain utilizing CISA when a State, Tribal, or local government has formally adopted, through code or other formal adoption measures, a tool, resource, or other written standards that provides data or other methods to identify the FFRMS floodplain using CISA for a particular project. In addition, HUD may identify additional tools, resources, or other processes that a responsible entity may voluntarily use to define the FFRMS floodplain using CISA. HUD or a responsible entity has the option to utilize a tool, resource, written standard, or other process permitted in § 55.7(f) where it results in an elevation that is at least as high as the lowest of (1) the 0.2-percent-annual-chance floodplain elevation; (2) the elevation that results from adding an additional two feet to the base flood elevation; or (3) the elevation required by paragraphs (b) or (c) of § 55.7, if CISA data is available and actionable under paragraphs (b)(1) or (c)(1). Where HUD or a responsible entity voluntarily defines the FFRMS floodplain using the options in paragraphs (f)(1)(i) or (f)(1)(ii) of § 55.7, the criticality of the action must be considered when determining the appropriate elevation of the FFRMS floodplain.

C. Revised Definitions

This final rule revises various definitions in 24 CFR 55.2. The definitions are revised as follows:

Best available information: The final rule relocates the definition of ''best available information'' from within the definition of coastal high hazard area in 24 CFR 55.2 to two new sections, 24 CFR 55.7 and 55.8. The final rule also adjusts the definitions of ''0.2-percent-annual-chance (500-year) floodplain,'' ''floodway,'' and ''1-percent-annual-chance (100-year) floodplain,'' to reflect these new citations.

Sources of best available information for identifying the FFRMS floodplain are described in 24 CFR 55.7 according to CISA, 0.2-Percent-Annual-Chance Flood Approach, and FVA methods. Best available information sources for floodways, coastal high hazard areas, and areas within the Limit of Moderate Wave Action (LiMWA) are identified in 24 CFR 55.8 and include effective and advisory or preliminary FEMA analysis reflected in FEMA's maps.

Critical action: The final rule revises the definition of ''critical action'' to include community stormwater management infrastructure and water treatment plants as examples of utilities or services that could become inoperative during flood and storm events.

Federal Flood Risk Management Standard (FFRMS) floodplain: The final rule adds the definition of FFRMS floodplain.

0.2 percent-annual chance floodplain: The final rule updates the definition of ''0.2-percent-annual-chance floodplain'' to be consistent with the new definition of FFRMS floodplain. The final rule also removes the statement that the 0.2-percent-annual-chance floodplain is the minimum area of concern for critical actions, which is not consistent with HUD's implementation of FFRMS when CISA data is available and actionable.

Impervious surface area: The final rule adds the definition of ''impervious surface area'' to provide an objective criterion for use in §§ 55.8(a)(1), 55.12, and 55.14.

Limit of Moderate Wave Action (LiMWA): The final rule adds the definition of ''Limit of Moderate Wave Action (LiMWA).'' The LiMWA is the

[22] All HUD programs, with the exception of programs that are not subject to NEPA (*e.g.,* the Federal Housing Administration single family program and the Housing Trust Fund), are subject to part 55. Certain projects may be exempt from part 55 based on project activities, as discussed in § 55.12 of this final rule.

inland limit of the portion of Coastal A Zone where wave heights can be between 1.5 and 3 feet during a base flood event, subjecting properties to damage from waves and storm surge.[23] The area on the flood map between the coastal high hazard area (Zone V) and the LiMWA is called the Coastal A Zone, and laboratory tests have consistently confirmed that wave heights within the Coastal A Zone can cause significant damage to structures that are not constructed to withstand coastal hazards.[24] Consistent with the risks posed by these coastal hazards, this final rule requires structures within the Coastal A Zone to be built to Zone V standards.

New construction: The final rule removes the definition for new construction from § 55.2 and incorporates it into a new § 55.10, ''Limitations on HUD assistance in wetlands.'' The definition is also revised to provide additional context on construction actions.

Wetlands: The final rule revises the definition for ''wetlands'' by removing the part of the definition that described how wetlands are determined and moves that description to a new § 55.9, ''Identifying wetlands.'' The final rule also removes the non-exhaustive list of examples of what does not constitute a wetland because it is not necessary to list things that the definition does not cover and in order to avoid confusion about certain areas around deep water aquatic habitats that may be considered wetlands.

D. Assignment of Responsibilities

This final rule clarifies in 24 CFR 55.3 that HUD Assistant Secretaries, the HUD General Counsel, and the President of the Government National Mortgage Association shall take responsibility for all decisions made under their jurisdictions that are made pursuant to the decision making process in 24 CFR 55.20. The final rule also revises the duties of grantees and applicants for clarity and adds a new § 55.3(f) that codifies the role of third-party providers.

E. Notification of Floodplain Hazard

This final rule revises HUD's regulations requiring notification of floodplain hazard. The notification requirements in 24 CFR 55.21 and conveyance restrictions in 24 CFR 55.22 are moved to a new 24 CFR 55.4. This creation of the new § 55.4 emphasizes the importance of providing notice as early in the process as possible. Section 55.4 retains the requirement that HUD (or HUD's designee) or the responsible entity must ensure that any party participating in a financial transaction for a property located in a floodplain and any current or prospective tenant is notified of the hazards of the floodplain location. In addition, 24 CFR 55.4 defines the notification requirements for property owners, buyers, developers, and renters and identifies specific hazards and information that must be included in these notices based on the interests of these parties.

The required information for owners, buyers, and developers includes the requirement or option to obtain flood insurance, the approximate elevation of the FFRMS floodplain, proximity of the site to flood-related infrastructure including dams and levees,[25] ingress and egress or evacuation routes, disclosure of information on flood insurance claims filed on the property, and other relevant information such as available emergency notification resources. For HUD-assisted, HUD-acquired, and HUD-insured rental properties, new and renewal leases are required to include acknowledgements signed by residents indicating that they have been advised that the property is in a floodplain and flood insurance is available for their personal property. Renters must also be informed of the location of ingress and egress or evacuation routes, available emergency notification resources, and emergency procedures for residents in the event of flooding. HUD encourages a proactive and systematic approach to notification requirements for properties in floodplains to ensure that prospective buyers and renters are made aware of potential flood risk with sufficient warning so that they can make risk-informed decisions.

The final rule also moves the conveyance restrictions for the disposition of multifamily real property from 24 CFR 55.22 to 24 CFR 55.4 with minimal changes to reflect updated floodplain terminology.

F. Flood Insurance

To address the issues of flood insurance requirements more comprehensively in the context of 24 CFR part 55 decision making, this final rule consolidates and moves all applicable flood insurance requirements to a new § 55.5. The flood insurance topic requirements covered in the new § 55.5 include Flood Disaster Protection Act (FDPA) limitations on HUD program participation for properties in communities not participating in FEMA's NFIP and on HUD disaster assistance for property damage in a special flood hazard area where previous flood disaster assistance required maintenance of flood insurance and the insurance was not maintained. In addition, § 55.5 includes the much more frequently applicable FDPA requirement for HUD-assisted projects regarding the mandatory purchase of flood insurance within the Special Flood Hazard Area (SFHA) as designated by FEMA on the effective FIRM or FIS, and the NFIP plays an important role in minimization measures to reduce flood losses.

The new § 55.5 also includes new language clarifying that HUD or the responsible entity may require flood insurance beyond the minimums established in the FDPA or by a State, locality, Tribe, or part 55 when necessary to minimize financial risk. Also, the new § 55.5 clarifies that mortgagees participating in a HUD assistance or mortgage insurance or guarantee program may impose additional flood insurance requirements.

While nothing in part 55 requires flood insurance outside of the SFHA, HUD strongly encourages that flood insurance be obtained and maintained for all structures within the FFRMS floodplain to mitigate financial losses. It may also be appropriate for high-value structures to maintain more flood insurance than is available under the NFIP. The maximum available building coverage through the NFIP is $250,000 for single family structures of one-to-four units and $500,000 for multifamily structures with five or more housing units and commercial structures.[26] For example, for FHA multifamily programs, the MAP Guide provides for flood insurance in an amount at least equal to the greater of: (1) the maximum flood insurance available for that type of property under the NFIP; or (2) an amount equal to the replacement cost of

[23] The LiMWA marks the inland limit of the ''Coastal A Zone,'' a term referenced by building codes and standards. The Coastal A Zone is the part of the coastal Special Flood Hazard Area (SFHA) where wave heights can be between 1.5 and 3 feet during the base flood event, see *https://www.fema.gov/sites/default/files/documents/fema_coastal-glossary.pdf.*

[24] *See, e.g.,* Federal Emergency Management Agency, National Flood Insurance Program, Answers to Questions About the NFIP, available at *https://agents.floodsmart.gov/nfip-answers-to-questions.*

[25] Proximity to flood control infrastructure can be identified through the U.S. Army Corps of Engineers' National Levee Database and National Inventory of Dams, *https://levees.sec.usace.army.mil/.*

[26] *See* FEMA, Flood Insurance and the NFIP Fact Sheet (June 14, 2021), available at *https://www.fema.gov/fact-sheet/flood-insurance-and-nfip.*

the bottom two stories above grade.[27] For larger structures in more expensive areas, it may be necessary to obtain private flood insurance to insure up to the full replacement cost of the structure or owners may risk catastrophic financial losses even with NFIP coverage.

G. Compliance

This final rule creates a new § 55.6 regarding complying with the requirements for floodplain management and protection of wetlands by outlining the process HUD or the responsible entity must follow to determine whether compliance with part 55 is required. The new § 55.6 also describes how to determine whether the 8-step decision making process [28] is required and whether the proposed action would require notification and flood insurance. The new § 55.6 does not create any new requirements but, to assist practitioners, § 55.6 does provide a process to comply with part 55. The new § 55.6 also moves a summary of documentation requirements from § 55.27 to § 55.6(d).

This final rule also creates a new section regarding limitations on HUD assistance in floodplains at § 55.8 and revises § 55.10 to address the topic of limitations on HUD assistance in wetlands. Sections 55.8 and 55.10 largely maintain the restrictions that existed prior to this final rule but with some revisions and additions. For example, § 55.8(b) maintains the current requirement that all decisions be based on the best available flood data provided by FEMA unless the current effective data indicates a higher flood risk than interim or preliminary sources.

In order for HUD assistance to be used in a proposed activity, § 55.8(c) requires that HUD or the responsible entity take measures to address repeat flood losses associated with structures identified by FEMA as Severe Repetitive Loss (SRL) properties.[29] When FEMA has approved improvements designed to prevent repeated flood losses at the SRL property and communicated these to the property owner, completion of this FEMA-identified mitigation qualifies the structure to be listed as ''Mitigated'' and may reduce the flood insurance premium of the SRL property. To ensure that HUD substantial improvement, reconstruction, or new construction funding and HUD-required mitigation identified in the 8-step decision making process delivers this benefit, under § 55.8(c) HUD or the responsible entity must identify and incorporate the FEMA identified SRL mitigation within Step 5 (minimization of impacts) of the 8-step decision making process at § 55.20. The intent of this addition is to preserve lives and property, avoid repeated flood losses, potentially reduce flood insurance costs, and ensure that HUD-identified mitigation at a minimum meets the level of mitigation required by FEMA to be listed as ''Mitigated'' in its NFIP database.

H. Incidental Floodplain Exception

For purposes of defining when projects with onsite floodways may proceed, this final rule removes floodways, as well as coastal high hazard areas and the LiMWA, from the incidental floodplain exception at § 55.12(c)(7) and replaces it with the new § 55.8(a)(1), which covers limitations on HUD assistance in floodways. The new § 55.8(a)(1) clarifies that HUD assistance may be used in floodways in two circumstances:

1. Where an exception in § 55.12 applies. This is not a change from HUD's existing regulations.

2. Where all structures and most improvements are removed from the floodway and a permanent covenant or comparable restriction would prevent future development or expansion of existing uses in the floodplain and/or wetland. Rehabilitation activities, including reconstruction in the case of Presidentially declared disasters, that do not expand existing uses in the FFRMS floodplain outside of the floodway are permitted under the new § 55.8. This exception combines aspects of the existing exceptions for floodplain restoration activities and incidental floodplains and allows for limited improvements in the floodway, including functionally dependent uses, utility lines, de minimis improvements, and removal of existing structures or improvements. This option allows for a broader range of activities in the floodway and in the adjacent FFRMS floodplain than is permitted under the current incidental floodplain exception. This option does require projects with onsite floodways to complete the 8-step decision making process in § 55.20 and determine that there are no practicable alternatives before approving any proposed activity on a site that includes a floodway.

This final rule maintains a narrower version of the existing incidental floodplain exception as applied to the FFRMS floodplain (not including floodways, coastal high hazard areas, or within the LiMWA) in the revised § 55.12(g). The revised § 55.12(g) allows projects to proceed without completing the 8-step decision making process where an incidental portion of the project site falls within the FFRMS floodplain.

I. Identifying Wetlands and Limitations on HUD Assistance in Wetlands

This final rule adds a new § 55.9 and revises § 55.10 to address issues regarding wetlands identification and HUD's limitations on work impacting wetlands.

The new § 55.9, ''Identifying Wetlands,'' builds on the definition of ''wetlands'' in § 55.2(b)(13) by clarifying common areas of confusion and removes unnecessary procedural requirements. Section 55.9 revises HUD's current regulations to address limitations associated with the exclusive use of the National Wetlands Inventory (NWI) for wetlands screening.[30] This final rule broadens the wetlands definition beyond NWI screening alone and addresses the potential for data gaps or outdated information by requiring that HUD and

[27] *See* MAP Guide, sec. 3.9.2.3, available at *https://www.hud.gov/program_offices/administration/hudclips/guidebooks/hsg-GB4430. See also* form HUD–92329, available at *https://www.hud.gov/program_offices/administration/hudclips/forms/hud9*. Per the NFIP definition, the grade level is defined as the lowest or highest finished ground level that is immediately adjacent to the walls of the building. Use natural (pre-construction), ground level, if available, for Zone AO and Zone A (without BFE).

[28] For a discussion of the decision making process in the *Guidelines, see Guidelines for Implementing Executive Order 11988, Floodplain Management, and Executive Order 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input* (October 8, 2015).

[29] SRL properties are defined following current FEMA standards. In its April 2020 NFIP Flood Insurance Manual, FEMA designates NFIP-insured single family or multifamily residential buildings as SRL where:

1. The building has incurred flood-related damage for which four or more separate claims payments have been made, with the amount of each claim (including building and contents payments) exceeding $5,000, and with the cumulative amount of such claims payments exceeding $20,000; or

2. At least two separate claims payments (building payments only) have been made under such coverage, with the cumulative amount of such claims exceeding the market value of the building.

In both instances, at least two of the claims must be within 10 years of each other, and claims made within 10 days of each other will be counted as one claim. In determining SRL status, FEMA considers the loss history since 1978, or from the building's construction if it was built after 1978, regardless of any changes in the ownership of the building. The term ''SRL property'' refers to either an SRL building or the contents within an SRL building, or both. The most recent designations can be found in Appendix I of the April 2020 NFIP Flood Insurance Manual, available at *https://www.fema.gov/sites/default/files/2020-05/fim_appendix-i-severe-repetitive-loss-properties_apr2020.pdf*.

[30] The U.S. Fish and Wildlife Service maintains the NWI. For more information regarding the NWI, see the U.S. Fish and Wildlife Service's National Wetlands Inventory website, available at *https://www.fws.gov/program/national-wetlands-inventory*.

responsible entities supplement the NWI with a visual observation of the property to assess wetlands indicators. Where these sources do not provide a conclusive answer as to whether a wetland is present, practitioners may use one of three methods to determine the presence or absence of a wetland: (1) consultation with the U.S. Fish and Wildlife Service (USFWS); (2) reference to other Federal, State, and/or local resources and site analysis by the environmental review preparer; or (3) a wetlands evaluation prepared by a qualified wetlands scientist. This process of determining the presence or absence of a wetland increases flexibility and avoids unnecessary consultation with the USFWS without increasing the risk that wetlands will not be accurately identified.[31]

The revised § 55.10, ''Limitations of HUD Assistance in Wetlands,'' explicitly defines the procedural requirements for projects with the potential to directly or indirectly impact on- or off-site wetlands. These revisions to § 55.10 codify and clarify existing policies on wetlands compliance without imposing new requirements.

J. Clarification and Revisions of Exceptions

This final rule breaks down the exceptions in the current § 55.12(a)–(c) into three separate sections, §§ 55.12, 55.13, and 55.14. This revision improves the overall clarity of the three distinct categories of excepted activities: (1) those that are excluded from all compliance with part 55 (§ 55.12); (2) those that must comply with the standards and limitations in part 55, such as prohibitions on activities in floodways but that are not required to complete the 8-step decision making process (§ 55.13); and (3) those that may complete the modified 5-Step decision making process in lieu of the full 8-step decision making process (§ 55.14). Beyond this revision, the final rule makes only limited changes to the exceptions themselves.

1. Exceptions in § 55.12

Based on HUD's experience and activities reflected in environmental review records for floodplain restoration projects, this final rule provides flexibility for floodplain-compatible parks and recreation uses routinely combined with floodplain and wetland restoration and preservation work. In the revised 24 CFR 55.12, ''Inapplicability of 24 CFR part 55 to certain categories of proposed actions,'' this final rule expands on the existing exception for floodplain and wetland restoration and preservation activities to allow certain structures and improvements designed to be compatible with the beneficial floodplain or wetland function of a property.

Two exceptions are removed through this final rule. The exception for sites where FEMA has issued a Letter of Map Amendment (LOMA) or Letter of Map Revision (LOMR) in the current § 55.12(c)(8) is removed. HUD is removing the exception described in the current § 55.12(c)(8)(i) because a FEMA determination, through the LOMA/LOMR process, that a location is outside of the 1-percent-annual-chance floodplain or above base flood elevation is not intended to state whether the location is or is not within the FFRMS floodplain. HUD is removing the exception described in the current § 55.12(c)(8)(ii) on conditional LOMAs and conditional LOMRs for the same reason, as well as because this exception can incentivize adding fill in a floodplain in a manner that reduces floodplain function in adjoining areas by excepting such actions from compliance with part 55. HUD is changing this policy to disincentivize the use of sitewide fill and require completion of the 8-step decision making process before adding fill to modify a floodplain.

HUD is also removing the exception described in the current § 55.12(c)(11) for projects related to ships and waterborne vessels because these are not activities that generally receive HUD funds and practitioners have expressed confusion over its presence in the rule.

2. Exceptions in §§ 55.13 and 55.14

The final rule makes minimal changes to the activities listed in the current § 55.12(a) and (b), which must comply with the requirements in part 55 but do not trigger the full 8-step decision making process. The final rule makes clarifying changes to the requirements currently listed in § 55.12(a)(3) and (4) that the footprint of the structure and paved areas are not significantly increased. Through this final rule, the new § 55.14(c) and (d) require that the footprint of the structure and paved areas are not increased by more than 20 percent. The final rule also includes a clarification for the requirement currently listed in § 55.12(b)(5)(iii) that the approval of financial assistance to lease an existing structure located in the floodplain requires that the structure be insured to the maximum in order to meet the exception. This existing provision was inadvertently omitted from the text of the proposed rule. The final rule provision also clarifies that this exception applies to financial assistance to lease both an existing structure and units within an existing structure.

Notably, the final rule adds two new exceptions:

1. *Section 55.13(f).* For special projects dedicated to improving energy or water efficiency of utilities or installing renewable energy that do not meet the threshold for substantial improvement, the new § 55.13(f) limits procedural hurdles to energy or water efficiency retrofit projects, which have limited potential to adversely affect floodplains or wetlands.

2. *Section 55.14(e).* For repairs, rehabilitation, or replacement of certain infrastructure with limited impact on impervious surface area, including streets, curbs, and gutters, § 55.14(e) provides an exception for smaller scale infrastructure projects that had been lacking from part 55. This added exception does not apply to critical actions, levee systems, chemical storage facilities (including any tanks), wastewater facilities, or sewer lagoons, all of which would require the 8-step decision making process.

K. 8-Step Decision Making Process

For actions that trigger the 8-step decision making process in whole or in part, the final rule makes several revisions to § 55.20 to implement FFRMS, clarify proper completion of each of the 8 steps of the decision making process, and otherwise modernize requirements. These revisions include:

1. Codifying roles and responsibilities in the 8-step decision making process, which have been frequently misunderstood.

2. Editing for consistency with FFRMS and new paragraphs on identification and limitations associated with the FFRMS floodplain and wetlands.

3. Adding an option to publish public notices in Steps 2 and 7 on an appropriate government website as an alternative to a printed news medium.

4. Inserting further clarifications and examples of required and suggested analysis.

5. Adding a requirement to coordinate the 8-step decision making process with any public engagement process associated with environmental justice, where project planners are also engaging stakeholders. This is consistent with the policy goals of Executive Order 14096, ''Revitalizing Our Nation's Commitment

[31] This approach is specific to HUD's regulations and differs from the United States Army Corps of Engineers' (USACE) current process for jurisdictional wetland determination identified in the USACE Wetland Delineation Manual.

to Environmental Justice.'' [32] HUD intends to issue updated guidance on advancing environmental justice.

L. Elevation, Floodproofing, Minimization, and Restoration

In addition to the revisions to § 55.20 previously described, this final rule significantly expands Step 5 in § 55.20(e) to implement FFRMS. Section 55.20(e) of the final rule provides that, in addition to the current mitigation and risk reduction requirements, all new construction and substantial improvement actions in the FFRMS floodplain subject to the 8-step decision making process must be elevated or, in certain cases, floodproofed above the FFRMS floodplain. If higher elevations, setbacks, or other floodplain management measures are required by State, Tribal, or locally adopted code or standards, HUD will require that those higher standards apply. The revised § 55.20(e) also provides more specific instruction on minimization and floodplain restoration measures, which are a key component of increasing flood resilience and must be considered in the 8-step decision making process.

For non-critical actions that are non-residential structures or multifamily residential structures that have no residential dwelling units below the FFRMS floodplain, through § 55.20(e)(1)(ii) of this final rule, new construction and substantial improvement projects may, as an alternative to being elevated above the FFRMS floodplain, be designed and constructed such that, below the FFRMS floodplain, the structure is floodproofed. Except for changing ''base flood level'' to ''FFRMS floodplain,'' as defined in § 55.7, this final rule adopts FEMA's requirements for floodproofing as provided in FEMA's regulations at 44 CFR 60.3(c)(3)(ii) and 60.3(c)(4)(i). In summary, all substantially rehabilitated or newly constructed structures within the FFRMS floodplain which are not elevated must be floodproofed consistent with the latest FEMA standards at or above the level of the FFRMS floodplain. This provision permits owners of non-residential and certain residential buildings to construct structures in a way that is less expensive than elevating but allows the buildings to withstand flooding, thus appropriately balancing property protection with costs and reflecting the lower risk to human life and safety in non-residential structures or parts of structures.

In the case of residential buildings, § 55.20(e)(1) of this final rule provides that the term ''lowest floor'' must be applied consistent with FEMA regulations in 44 CFR 59.1, FEMA's Elevation Certificate guidance, or FEMA's current guidance that establishes lowest floor.

Through this final rule, § 55.20(e)(2) identifies specific strategies that can reduce flood risk and loss of beneficial values of floodplains and wetlands, including green infrastructure, reconfiguration of the project footprint, and incorporation of resilient buildings standards. These strategies are based on floodplain and stormwater management best practices and HUD experience. Based on requests for technical assistance in this area, HUD believes the inclusion of recommended minimization measures will assist persons engaged in an 8-step decision making process.

This final rule also adds a new § 55.20(e)(3) to describe more clearly what is meant by restoration and preservation of wetlands or beneficial functions of the floodplain. Floodplain preservation is a concept that has been used in 24 CFR part 55 implementation historically but has been defined primarily through guidance, and this clarification is based on past practice and the successful incorporation of these measures in HUD-assisted projects.

Finally, this final rule replaces the current § 55.20(e)(3), which defines mitigation measures specific to critical actions, with a new § 55.20(e)(4). Section 55.20(e)(4) establishes mandatory actions to plan ahead for residents' safety in multifamily residential properties, healthcare facilities, and critical actions.

M. Processing for Existing Nonconforming Sites

This final rule creates a new § 55.21, ''Alternate processing for existing nonconforming sites,'' to address concerns about existing sites with onsite floodways. This section creates a special approval process for improvements to existing HUD-assisted or HUD-insured properties with onsite floodways under the following circumstances, summarized as:

1. HUD completes an 8-step decision making process and environmental review pursuant to part 50 and mandates measures to reduce flood risk and ensure that there are no other environmental risks or hazards at the site;

2. Specific measures will be taken to minimize flood risk and improve overall resilience at the site, including removing all residential units and critical action structures from the floodway; and

3. HUD determines that the HUD assistance cannot be practicably transferred to a safer site.

The purpose of this section is to establish a means of continuing HUD assistance or financing in exceptional circumstances to existing HUD-assisted or HUD-financed projects (*e.g.,* properties receiving assistance through Public Housing, Section 8 Project-based Rental Assistance, or subject to a HUD-insured mortgage) that would otherwise be unable to comply with part 55 due to the presence of an on-site floodway. This section should be applied only in very rare cases and is not intended to eliminate the general prohibition on providing HUD assistance for projects within floodways. However, HUD recognizes that there are circumstances in which terminating HUD assistance would not improve residents' overall resilience or safety in the context of HUD's mission. In such cases, HUD will closely review the site and determine whether the best option to improve flood resilience would be financing improvements at the existing site or rejecting HUD assistance at the site. The Assistant Secretary for Community Planning and Development has the authority to approve a project after HUD has met all of the conditions above.

N. Other Changes to Part 55

This final rule makes various other changes to part 55 to update terminology and references and restructures part 55 for readability and accuracy. Additionally, this final rule removes various provisions codified in part 55 that are outdated or underutilized.

The final rule removes § 55.24, ''Aggregation,'' because this provision is redundant with aggregation principles described more clearly in 24 CFR parts 50 and 58, which also apply to projects processed under 24 CFR part 55.

The final rule also removes the current § 55.25, ''Areawide compliance.'' Areawide decision making described in this section requires a complex notification process involving publications, and HUD has no record of the provision's use in a HUD-assisted activity since the promulgation of 24 CFR part 55. This provision is unnecessary because HUD has well-established procedures for tiering of environmental review records that similarly facilitate compliance with part

[32] E.O. 14096 builds on and supplements prior E.O.s. *See* 88 FR 25,251 (Apr. 26, 2023), *https://www.federalregister.gov/documents/2023/04/26/2023-08955/revitalizing-our-nations-commitment-to-environmental-justice-for-all.*

55 across a geographic area without relying on § 55.25.

The final rule relocates instructions on documenting 24 CFR part 55 decision making in the HUD environmental review record from § 55.27 to § 55.6 so that the instructions appear in context with general instructions on compliance with 24 CFR part 55 and a description of its structure. Additionally, the final rule revises the documentation requirements for consideration of alternatives to the proposed action to remove the requirement to compile a list of alternative properties in the local market. This information may be unavailable for some project types or not relevant to consideration of viable alternatives to achieve the goals of the decision making process within a given HUD program context.

The final rule removes § 55.28, which, in concept, provides relief from five of the eight steps in the wetlands decision making process when a permit has been secured from the United States Army Corps of Engineers (USACE) under Section 404 of the Clean Water Act for a proposed HUD-assisted construction activity in a jurisdictional wetland outside of the floodplain. The final rule removes this section because practitioners have not historically found it useful, and part 55 already contains another section that offers similar relief from the 8-step decision making process where USACE (or any other Federal agency) has already completed the 8-step decision making process for the same action. Section 55.26, which the final rule retains with revisions, allows HUD or responsible entities to adopt another agency or responsible entity's 8-step decision making process under conditions that are less restrictive than those in § 55.28, which apply to decision making under E.O. 11988 or E.O. 11990 carried out by USACE.

O. Minimum Property Standards

This final rule applies a new elevation standard to one-to-four-family residential structures with mortgages insured by FHA. Generally, in HUD's single family mortgage insurance programs, Direct Endorsement mortgagees submit applications for mortgage insurance to HUD, and Lender Insurance mortgagees endorse loans for insurance after the structure has been built. Thus, there is no HUD review or approval before the completion of construction. In these instances, HUD is not undertaking, financing, or assisting construction or improvements. Thus, the FHA single family mortgage insurance program is not subject to review under E.O. 11988, NEPA, or related environmental laws or authorities. However, newly constructed single family properties in HUD's mortgage insurance programs are generally required to meet HUD's Minimum Property Standards under 24 CFR 200.926 through 200.926e. These property standards require that when HUD insures a mortgage on a property, the property meets basic livability and safety standards and is code compliant. The section relating to construction in flood hazard areas, § 200.926d(c)(4), has long been included as a property standard.

In alignment with the revisions in this final rule that address FFRMS under E.O. 11988, this final rule also amends the Minimum Property Standards on site design, specifically the standards addressing drainage and flood hazard exposure at § 200.926d(c)(4). The purpose of the amendment of the property standards is to decrease potential damage from floods, increase the safety and soundness of the property for residents, and provide for more resilient communities in flood hazard areas. The final rule revises § 200.926d(c)(4) by requiring the lowest floor (including basements and other permanent enclosures) of newly constructed dwellings, within the 1-percent-annual-chance floodplain, to be at least 2 feet above the base flood elevation as determined by best available information. For one- to four-unit housing under HUD's mortgage insurance and low-rent public housing programs, HUD's Minimum Property Standards in 24 CFR part 200 currently require that a one- to four-unit property involving new construction, located in the 1 percent-annual-chance floodplain in the effective FIRM, be elevated to the effective FIRM base flood elevation. This final rule adds two feet of additional elevation to the base flood elevation as a resilience standard and applies this standard only to new construction of such properties and not to substantial improvement. This final rule does not require consideration of the horizontally expanded FFRMS floodplain for single family mortgage insurance projects governed by the requirements in the Minimum Property Standards.

P. Categorical Exclusion

This final rule amends § 50.20(a)(2)(i) to revise the categorical exclusion from further environmental review under NEPA for minor rehabilitation of one- to four-unit residential properties. Specifically, this final rule removes the qualification that the footprint of the structure may not be increased in a floodplain or wetland when HUD performs the review. In 2013, HUD removed the footprint trigger from the corresponding categorical exclusion at § 58.35(a)(3)(i) for rehabilitations reviewed by responsible entities. This change makes the review standard the same regardless of whether HUD or a responsible entity is performing the review. Moreover, when HUD performs a review under 24 CFR part 50, the categorical exclusion in § 50.20(a)(3) applies to construction, but not rehabilitation, of up to four units in a floodplain or wetland as an individual action such that an environmental assessment or environmental impact statement is normally not required. Rehabilitated structures in a floodplain or wetland with an increased footprint currently require an environmental assessment or environmental impact statement.[33] It is logically inconsistent to require a greater review for minor rehabilitations than new construction. Similarly, it is logically inconsistent to apply a higher level of review for HUD as opposed to grantees because the proposed actions would be the same regardless of review authority under 24 CFR part 50 or part 58.

Actions under this revised categorical exclusion remain subject to E.O. 11988, E.O. 11990, and part 55, and any impact resulting from an increased footprint in a floodplain or wetland will be fully addressed by the 8-step decision making process in part 55.

Q. Permitting Online Posting

This final rule updates §§ 50.23, 58.43, 58.45, and 58.59 to allow public notices to be posted on an appropriate government website as an alternative to publication in local news media if the appropriate government website is accessible to individuals with disabilities and provides meaningful access to individuals with Limited English Proficiency. This change makes parts 50 and 58 consistent with revised § 55.20, which allows public notices required as part of the 8-step decision making process to be posted on a government website instead of in a newspaper.

R. Severability

This final rule incorporates a new severability provision in a new subpart D, at § 55.30. As described in § 55.30, it is HUD's intent that each provision of this final rule has effect to its fullest extent permitted by law, including by ensuring the severability of any provision affected by a judicial order. Should a court find any specific portion of this final rule unenforceable, the

[33] *See* § 50.20(a)(3)(iii).

remainder of this final rule and its application should remain effective to the fullest extent permitted by law. Those portions that are unaffected by any judicial ruling can be implemented by HUD without a new rulemaking simply to promulgate provisions that are not subject to a court ruling. For example, this final rule revises standards in both 24 CFR parts 55 and 200. The administration and workability of each part are independent; and so, severing a portion of the revision to one part would not affect the administration and workability of the revisions in the other part. Similarly, severing one program from the application of this final rule would not affect the administration and workability of its application to other HUD programs. As another example, severing one approach for identifying the FFRMS floodplain described in § 55.7 would not affect the validity and administration of the remainder of § 55.7, nor the remaining portions of this final rule.

S. Tribal Consultation and Stakeholder Listening Sessions

HUD's Government-to-Government Tribal Consultation Policy calls for consultation with Tribal Nations and Tribal Leaders early in the rulemaking process on matters that have Tribal implications. Accordingly, on June 10, 2021, HUD sent letters to all eligible funding recipients under the Native American Housing Assistance and Self Determination Act of 1996 (NAHASDA) and their tribally designated housing entities informing them of the nature of the forthcoming rule and soliciting comments. This letter announced a 30-day comment period and a webinar and conference call consultation session regarding the forthcoming rule. On August 18, 2021, HUD sent a second letter with a 60-day comment period to review an early draft of the proposed regulatory changes. During this period, HUD held an additional consultation session via webinar and conference call. This letter was posted on Codetalk, the HUD Office of Native American Programs' website, along with an early outline of the rule. During this draft review period, HUD received one written comment, suggesting that HUD explicitly recognize the right to Tribal self-governance in part 55. HUD acknowledges the sovereignty of federally recognized American Indian and Alaska Native Tribes and is committed to operate within a Government-to-Government relationship to allow Tribes the maximum amount of responsibility for administering their housing programs. Tribes had the opportunity to comment on this rule at the proposed rule stage.

During the comment period of the proposed rule, HUD engaged in additional stakeholder outreach through four live listening sessions held April 17, 2023, May 2, 2023, May 4, 2023, and May 15, 2023. While all sessions were free and open to the public, local government officials, Tribal representatives, housing industry representatives, and the general public each had a session targeted towards their respective organizations or groups. These sessions were intended as informative listening sessions in which HUD provided an overview of the proposed rule and an opportunity for members of the public to comment. Notes from the listening sessions can be found at *https://www.hud.gov/program_offices/comm_planning/environment_energy/ffrms.*

T. Delayed Compliance Date

This final rule has an effective date of *May 23, 2024;* however, required compliance with this final rule is delayed until June 24, 2024, except: compliance with this final rule's amendments to 24 CFR part 200 is required for new construction where building permit applications are submitted on or after January 1, 2025; and compliance with this final rule's amendments to 24 CFR part 55 is required no later than January 1, 2025 for the following programs: (1) Programs subject to chapter 9 of the MAP Guide (Multifamily FHA, Section 202 and 811 capital advance grants, transfers under Section 8(bb) of the United States Housing Act and Section 209 of HUD's annual appropriations (or subsequent provisions), Section 8 Renewals with Capital Repairs, RAD conversions to PBRA, and Green and Resilient Retrofit Program); and (2) The other mortgage insurance programs subject to part 55 (FHA Healthcare and FHA Risk Share).

After reviewing public comments, HUD has determined, in certain instances, to provide a delayed compliance period to allow entities regulated by this rule a grace period to come into compliance with the revised requirements. As described, compliance with the amendments to part 200 of this rule is required for new construction where building permit applications are submitted on or after January 1, 2025. This delay is intended to provide home builders ample opportunity to adapt and prepare for the requirements of this rule, including the increased elevation standards. Setting a delayed compliance period for the amended requirements for part 200 is appropriate to address public comments received expressing concern that the rule could limit the availability of single family affordable housing. Applications for single family FHA insurance are submitted to HUD after housing construction is completed. As a result, for new construction located in Special Flood Hazard Areas, applications submitted to HUD following implementation of this rule will be rejected if they do not meet the elevation requirements in the Minimum Property Standards. HUD is extending the compliance date for the part 200 revisions to allow time for housing developers to incorporate the new Minimum Property Standards into the planning process for new construction.

Similarly, after reviewing public comments, HUD has determined to provide a delayed compliance period until January 1, 2025, for entities to come into compliance with the revisions this final rule makes to part 55 for the following programs: (1) Programs subject to chapter 9 of the MAP Guide (Multifamily FHA, Section 202 and 811 capital advance grants, transfers under Section 8(bb) and under Section 209 of HUD's annual appropriations (or subsequent provisions), Section 8 Renewals with Capital Repairs, RAD conversions to PBRA, and the Green and Resilient Retrofit Program); and (2) The other mortgage insurance programs subject to part 55 (FHA Healthcare and FHA Risk Share). Setting a delayed compliance period for the revised part 55 is appropriate for these programs to account for the extensive lead time required for site design, planning, and environmental analysis, all of which are required prior to submitting an application for FHA mortgage insurance. Many mortgage insurance projects include large-scale development that requires significant time and monetary investment in planning initiatives, thereby requiring a longer compliance period to incorporate part 55 revisions into the planning process. Additional programs subject to the MAP Guide have similar project planning timelines. The delayed compliance period poses limited increased flood risk for these programs in the interim because the MAP Guide currently requires elevation to BFE +2 feet for new construction, which is one of the methods for defining the FFRMS floodplain under this rule.

III. Changes at the Final Rule Stage

In response to comments received during the proposed rule stage of this rulemaking, HUD is making several revisions to the final rule:

Part 50 (Authority). The final rule revises the authority section at the beginning of part 50 to update the

authority of ''42 U.S.C. 4321–4335'' to ''42 U.S.C. 4321–4336e.'' This change to the citation to NEPA is appropriate because the Fiscal Responsibility Act of 2023 (Pub. L. 118–5) added additional sections to NEPA.

Part 55 (Authority). The final rule revises the authority section at the beginning of part 55 to add the authority 42 U.S.C. 4321 *et seq.* This change to include NEPA is appropriate because NEPA requires the Federal government to act as a ''trustee of the environment'' for future generations.

Section 55.2. In § 55.2(b)(12), the final rule, in paragraphs (i)(A) and (i)(B), clarifies that the repair, reconstruction, modernization, or improvement of a structure includes a manufactured housing unit. In § 55.2(b)(13), the final rule also removes the non-exhaustive list of examples of what does not constitute a wetland because it is not necessary to list things that the definition does not cover and in order to avoid confusion about certain areas around deep water aquatic habitats that may be considered wetlands.

Section 55.4. In § 55.4(b), the final rule adds the term ''HUD-acquired'' to the list of property types to clarify that properties that had been previously insured by HUD and were then acquired by HUD through default are also subject to the requirements for notification to renters when a property is in a floodplain.

Section 55.6a. The final rule adds a new section regarding severability at § 55.6a, which describes that any portion of this rule found to be unlawful shall be severable from this rule and the remainder of the part shall continue to remain effective.

Section 55.7. The final rule adds language to § 55.7(b)(1) and (c)(1) to clarify when HUD considers data to be available and actionable to define the FFRMS floodplain using CISA. The final rule also adds language to 55.7(e) to clarify that CISA must be used for EIS level projects where available and actionable data exists or can be generated. Additionally, the final rule adds language to § 55.7(f) to clarify that HUD and responsible entities may utilize local tools to implement CISA on a voluntary basis, as long as the resulting elevation is at least as high as the lowest of (1) the 0.2-percent-annual-chance flood elevation; (2) the elevation that results from adding an additional two feet to the base flood elevation; or (3) the elevation required by paragraphs (b) or (c) of § 55.7, if CISA data is available and actionable under paragraphs (b)(1) or (c)(1). The final rule also permits the voluntary use of any particular tool, resource, or other process that defines the floodplain using CISA that HUD identifies through guidance.

Section 55.8. In § 55.8(a)(1)(ii), the final rule expands the scope of activities allowed in the FFRMS floodplain where there is a floodway onsite to include rehabilitation that does not expand the footprint of existing buildings or the number of units on the site. In § 55.8(a)(1)(ii)(B), HUD removed specific examples of de minimis improvements from the rule. HUD intends to provide more detailed guidance on de minimis improvements to ensure that only compliant work is allowable under this part. In § 55.8(a)(2), the final rule clarifies that certain critical actions may be located in the floodway if they are functionally dependent and any existing or new structure has been or will be elevated or floodproofed to the FFRMS elevation for critical actions; and that certain critical actions may be located in a coastal high hazard area or LiMWA if they are functionally dependent and meet FEMA's mitigation requirements for such actions located in the coastal high hazard area. This section also clarifies that for critical actions, mortgage insurance on a property containing a floodway may be exempt from the prohibition in § 55.8(a)(2) if there are no structures or improvements located in the floodway, and subject instead to § 55.8(a)(1).

Section 55.9. In § 55.9(a), the final rule makes minimal changes to align the text of § 55.9(a) with § 55.10.

Section 55.10. In § 55.10(a), the final rule clarifies, through an added example, that new construction activities for a proposed project include related activities for any structures or facilities including the siting of new manufactured housing units.

Section 55.12. The final rule excludes the proposed § 55.12(g)(3) so as to avoid duplication and to better align with both existing processes and new incidental floodway provisions.

Section 55.13. In § 55.13(e), the final rule clarifies that the exception to § 55.20 applies to financial assistance to lease an existing structure and/or units within an existing structure, adds paragraph (e)(3), which was unintentionally omitted from the proposed rule and aligns with existing regulatory language, and specifies in paragraph (e)(3) that the structure should be insured to the maximum extent available under the NFIP. In § 55.13(f), the final rule clarifies that the exception applies to special projects for the purpose of improving the ''energy or water efficiency'' of utilities rather than the ''efficiency'' of utilities. The final rule excludes the proposed 55.13(g) exemption to avoid unnecessary duplication. HUD determined that both the Section 184 Indian Housing loan guarantee program and the Section 184A Native Hawaiian Housing loan guarantee program meet the categorical exclusion at 24 CFR 50.19(b)(17), which is already exempt from part 55 under § 55.12(b).

Section 55.16. In Table 1 to § 55.16, the final rule clarifies that certain critical actions may be located in the floodway, coastal high hazard area, and LiMWA, if they meet the requirements for critical actions in § 55.8.

Section 55.20. The final rule adds a new paragraph (e)(2)(iv) to § 55.20 to clarify that, if applicable, minimization techniques include identifying and incorporating FEMA identified Severe Repetitive Loss mitigation as outlined in § 55.8(c). The final rule also makes minimal changes to § 55.20(a) to align the language with § 55.10. The final rule also adds nature-based approaches as an alternative method for avoiding impacts to wetlands and floodplains in § 55.20(c)(1)(ii). Additionally, the final rule makes other changes to eliminate redundant language.

Section 55.21. The final rule revises the layout of § 55.21(b) to improve readability. Additionally, § 55.21(b) adds minimum requirements for proposed projects to meaningfully reduce flood risk and increase the overall resilience of the site, including a No-Rise Certification for any new improvements in the floodway.

Section 55.30. The final rule adds a new section regarding severability at § 55.30, which describes that any portion of this rule found to be unlawful shall be severable from this rule and the remainder of the part shall continue to remain effective.

Part 58 (Authority). The final rule revises the authority section at the beginning of part 58 to update the authority of ''42 U.S.C. 4321–4335'' to ''42 U.S.C. 4321–4336e.'' This change to the citation to NEPA is appropriate because the Fiscal Responsibility Act of 2023 (Pub. L. 118–5) added additional sections to NEPA.

Section 200.926. The final rule removes the proposed revision to § 200.926(a) that would have applied the elevation standard in § 200.926d(c)(4)(i) through (iii) to substantial improvement activities. In response to public comments received, HUD determined to not include the proposed change to § 200.926(a) in the final rule to avoid creating adverse impacts on homeowners renovating their existing single family homes in low-cost areas.

Section 200.926d. The final rule does not apply § 200.926d elevation requirements to substantial improvement activities. The final rule also clarifies that for the elevation certificate required by § 200.926d(c)(4)(iii), HUD's elevation standard for newly erected manufactured housing is the standard required in 24 CFR 203.43f or 24 CFR part 3285, as applicable, rather than two feet above base flood elevation.

IV. Public Comments

This public comments section contains a summary of the public comments that HUD received in response to the proposed rule.

Specific Questions for Comment From the Proposed Rule

In section III.Q of the proposed rule, HUD included several specific questions for public comment. Those specific questions from the proposed rule and public comments received in response to those specific questions are summarized here, along with HUD's responses to the public comments received.

A. Question #1: Whether To Prioritize an Alternative Method Among the Three Approaches To Define the FFRMS Floodplain

1. General Support for the Proposed CISA Approach

Several commenters generally expressed support for HUD's goals outlined in the proposed rule, such as protecting safety, health and welfare, preserving natural floodplains, considering environmental justice impacts, preventing the significant impact of flooding on underserved communities, and more accurately measuring flood risk. One commenter emphasized that it was HUD's fiscal obligation to regulate the FFRMS floodplain using CISA to reduce the Federal government's fiscal exposure to climate change. Another commenter strongly supported HUD's assessment to subject more of the floodplain area to the 8-step decision making process and encouraged HUD to solidify the basic purpose and guidance in 24 CFR 55.1(a)(5) of the proposed rule. The commenter emphasized the importance of HUD's commitment because flooding—even inland flooding—is becoming more frequent across the U.S. coastline, due to climate change, no matter how it is measured.

Several commenters expressed support for the three-tiered approach for defining the FFRMS floodplain outlined in the proposed rule. These commenters also agreed that CISA should remain the primary method for determining the FFRMS floodplain. Commenters noted a preference for CISA because it is forward-looking, acknowledges ongoing advances in climate science, is more dynamic, and provides a more complete picture of flood risk over the lifetime of a project.

Several commenters also expressed their support for HUD's proposal to utilize the 0.2-Percent-Annual-Chance Flood Approach and the Freeboard Value Approach when CISA maps and analyses are not available. One commenter noted that where CISA floodplains cannot be implemented in the short- and medium-term, it is important to rely on proven standards that will give stakeholders tools that are well-understood and widely available.

Another commenter agreed with HUD that FEMA flood maps are often out of date and cited the White House Flood Resilience Interagency Working Group's Federal Flood Risk Management Standard CISA State of the Science Report in noting that the maps reflect that efforts to prioritize modernizing and implementing the NFIP are overdue. This commenter believed that the latest science on flood risk hazards demonstrates that there is sufficient data to regulate the FFRMS based on climate science and that it is critical the Federal government do so when the data are available in order to prevent risky planning and investment decisions.

One commenter emphasized that they support HUD's CISA-centered approach because it is likely that FEMA's 1-percent-annual-chance flood hazard measurements underestimate the number of assisted housing units within those areas. This commenter encouraged HUD to use CISA to the maximum extent possible. Another commenter agreed that continuing to use the 1-percent-annual-chance or even the 0.2-percent-annual-chance floodplain in place of CISA is irresponsible especially given HUD's mission of serving low-income families who are particularly ill-equipped to recover from flood-related hardships.

One commenter supported HUD's three-tiered approach prioritizing CISA, and added that since flood elevations are not static, a cautionary statement of reviewing the characteristics of flooding (velocity, debris, and flashiness) should also be considered for all proposals. Another commenter emphasized that no matter what approach was ultimately taken, it is important to streamline the FFRMS floodplain determination process and limit room for conjecture.

One commenter urged HUD to go further in its rule by requiring the evaluation of potential flooding throughout the design lifetime of structures using the best available risk modeling and science. This commenter said HUD should require project plans to account for expected flood heights and other mitigation measures. Another commenter requested HUD consider at minimum a 50-year projection for CISA and suggested HUD project larger floodplains because of the time necessary for climate instability to manifest. Another commenter recommended HUD use the same lower level of risk tolerance for critical and non-critical actions, arguing that the Federal government has a moral imperative to safeguard new and updated affordable housing by ensuring affordable housing can withstand climate change.

Several commenters asked HUD to incorporate some clarity in its final rule surrounding the meaning of ''anticipated life of the project.'' One commenter noted that it is not unusual for projects to extend beyond their anticipated life for years or even decades and that a project's extended life could impact the elevation for which they should be designed. Another commenter asked that HUD require CISA criteria to be extended over the entire life of a project—a minimum of 50 years, which is the length of time used for most building life cycle assessments.

HUD Response: HUD appreciates the support from commenters for HUD's goals outlined in the proposed rule. HUD disagrees that it is our fiscal obligation to regulate using CISA; however, we agree that it should be used as the preferred approach where data is available and actionable. HUD developed the three-tiered approach to defining the FFRMS floodplain with the intent to be more forward-looking and acknowledge that being flexible is necessary as science advances to best achieve the outlined goals. HUD appreciates commenters' feedback regarding the use of a multi-tiered approach and the importance of using proven standards when CISA is unavailable. HUD also appreciates the commenters' support that a wider floodplain area be considered in the 8-step decision making process, though HUD disagrees that this needs to be stated in 24 CFR 55.1(a)(5) because HUD considers the existing language sufficient and effective.

HUD also appreciates the commenters' considerations that FEMA FIRMs are static and based on a snapshot of data in time. HUD believes that its preferred approach, CISA, provides a significant advantage to provide future flood risk management.

HUD intends to publish guidance to help grantees choose appropriate design life horizons to utilize CISA effectively. The goal is for the chosen design life to protect the Federal investment throughout the anticipated life of the project without overly burdening projects with unreasonable elevation requirements. HUD notes that critical actions are given additional mitigation requirements as per the instructions in the Guidelines which ask Federal agencies to use higher standards for critical actions due to their more sensitive nature. This higher standard was considered too economically burdensome to impose on all projects with lower inherent risk, so it was not imposed for all activities. HUD intends that this rule will help protect Federal investments against future flood risk.

2. Concerns Regarding the Proposed CISA Approach

Several commenters also wrote in with concerns about HUD's approach for defining the FFRMS floodplain in its proposed rule.

a. Burden and Uncertainty

One commenter stated that the three-tiered definition of FFRMS floodplain was too confusing and burdensome. This commenter noted that establishing whether an action was in a floodplain or not is a critical first step in HUD's regulatory process given that if the action does occur in a floodplain, additional analysis and mitigation requirements are triggered. The commenter went on to say that without established floodplain maps, stakeholders will have a difficult time completing this first step and these material unknowns and uncertainties will generate increased project delays, increased project costs, and increased project cancelations—all at the expense of much-needed housing.

One commenter was specifically concerned with the horizontal floodplain definition. The commenter stated that FEMA's FIRMs are well-established and have clearly depicted the 1-percent-annual-chance floodplain in most communities across the Nation to the extent that many Federal, State, and local regulations are tied to the 1-percent-annual-chance floodplain. FEMA's maps regularly provide certainty to property owners to know when and where they must comply with a multitude of rules, codes, ordinances, and grant conditions.

HUD Response: HUD appreciates the commenters' feedback regarding the potential complexity of the tiered approach outlined in the proposed rule. As described earlier in this preamble in section II.B., the tiered approach to defining the FFRMS floodplain provides sufficient direction to grantees and applicants on how to determine if a project is located in the FFRMS floodplain based on data availability. Moreover, HUD intends to roll out ample training and technical assistance with this rule to ensure that grantees are well prepared to execute compliant environmental reviews. With training and assistance, HUD is confident that grantees will be able to navigate the process and avoid unnecessary negative effects on project timelines. This training will also help grantees work with their builders and avoid uncertainty associated with projects located in the FFRMS floodplain.

b. Local Data

Several commenters noted that some communities lack local, State, or Federal elevation data to establish the FFRMS floodplain with any of the three methods outlined in the proposed rule. These commenters suggested that this lack of available data could discourage developers and disproportionately impact rural communities that already have a lack of affordable housing. One commenter noted specifically that professional surveyors will not generally provide the 0.2-percent-annual-chance flood elevation without a formal flood study, which is not only very expensive but is also time-consuming. This commenter urged HUD to consider an alternative elevation for use in these circumstances. Another commenter also noted the expense of land surveys and the resulting decrease in housing that may result.

Conversely, one commenter noted they have created their own mapping tools to evaluate flood risk. This commenter is hoping to be able to continue using their tools and would like HUD to provide an approval process for using them. This commenter reiterated that one of HUD's stated goals is to better align with local standards that have already been strengthened and to take ''a flexible approach to adapt to the needs of . . . the local community.'' Commenters asked HUD to provide up to date maps and data to local communities and asked HUD to model FFRMS requirements after local codes.

One commenter hoped the FFRMS rule would encourage partnerships at all levels of government to adopt floodplain management policies. Another commenter suggested that HUD collaborate with state-level data providers to ensure that local data products meet CISA requirements and receive HUD approval. One commenter used the fact that many localities have made significant investments in ''down-scaled'' mapping of future flood risk as evidence that the availability of technically credible data on future flood risks has developed significantly since HUD's last proposed rule.

Another commenter urged HUD to incorporate local data that considers climate change by considering flood risk information available in each State's Hazard Mitigation Plan.

HUD Response: HUD appreciates the commenter's concerns regarding the availability of data in some communities. HUD understands that there are existing data limitations in some communities, particularly in rural areas, where FEMA mapping is unavailable. This rule does not change the current process and allows communities to utilize flood and elevation studies or best available data, including anything relevant from hazard mitigation plans, to proceed with their floodplain determination. Therefore, where FEMA FIRMs are not available, this rule has no impact on the current part 55 process to utilize best available information and would not have major cost impacts in those areas. The Regulatory Impact Analysis (RIA) did not offer evidence that the cost of surveys would have a significant impact on housing supply. Given the diversity of geography and data for HUD projects, HUD cannot set a standardized baseline elevation for all projects and instead must rely on a project-by-project approach.

As described earlier in this preamble, HUD appreciates that some State, Tribal, and local governments have created CISA tools capable of determining the extent of the FFRMS floodplain in their respective jurisdictions. As such, HUD has adjusted the language of this rule to voluntarily permit the use of local tools where they result in an elevation at least as high as the lowest of (1) the 0.2-percent-annual-chance floodplain elevation; (2) the elevation that results from adding an additional two feet to the base flood elevation or (3) the elevation required by paragraph (b) or (c) of § 55.7, if CISA data is available and actionable under paragraphs (b)(1) or (c)(1). While HUD will not model the FFRMS floodplain around local code requirements because it would lead to uneven protection standards nationwide, this change will better recognize the efforts many localities have made to address their own climate risks.

As part of the White House Flood Resilience Interagency Working Group helping to develop CISA tools nationwide, HUD appreciates the sentiment of commenters who wish to

encourage intergovernmental partnerships to adopt floodplain risk management policies. HUD relies on the Federal science agencies like FEMA and NOAA to work with their local partners to obtain accurate local flood risk data for use in their development of tools which may be used to implement CISA, as well as other FFRMS approaches. HUD is also open to coordinating with state-level providers on a project-specific basis as needed.

c. Federal CISA Implementation Tools

Several commenters agreed that, though they support forward-looking risk projections that consider climate change, it is premature to rely on CISA maps with national coverage, which may take years to develop. One commenter suggested that without stakeholder approval and practical application of tools, any proposed higher elevation requirements may be too severe and result in unintended, adverse consequences. Another commenter noted the opposite concern, that while CISA maps are being developed, older maps will need to be relied upon, which are insufficient. This commenter also noted that no funding is attached to HUD's proposed rulemaking.

One commenter stated that because a BFE based on CISA data cannot be used if the elevation is lower than the current FIRM or FIS and because there may be other environmental disclosure rules regarding climate flooding risk, this multilayered approach, reliant on maps that are not yet available, would create an impractical and untenable level of uncertainty for builders and developers. The commenter urged HUD to withdraw the proposed rule until maps of the floodplains were available and to release a CISA tool for public comment on the data, methodology, functionality, accuracy, and user friendliness of the model before it is implemented. The commenter also recommended the rule be subject to peer-review. If not, they predicted builders would have to do a lot of research and expend resources trying to determine if they were in a floodplain.

One commenter emphasized the complexity of developing a CISA mapping tool and recommended that HUD provide additional clarification on what process it will use to approve maps developed using CISA. The commenter suggested that this proposed rule should have focused more on the development of the mapping tool, and HUD may need to issue a separate notice seeking comment from the public on the tool's development given the complexity of the development process. Specifically, the commenter recommends HUD seek input from stakeholders and industry participants, as their input is critical for the tool's eventual success.

Several other commenters also requested the opportunity to provide feedback on CISA maps. One commenter noted that they would like to provide further comment on a focused handful of HUD's actionable modeling criteria. Other commenters asked whether CISA maps would be available for stakeholders to identify the FFRMS floodplains and whether HUD would require approval for a process that would result in FFRMS floodplain boundaries different than what a user would generate using CISA mapping. These commenters also asked who would approve CISA maps and by what process and what qualifications HUD's approver would have to determine the CISA maps' sufficiency.

Another commenter noted that it is critical for HUD to define the specific circumstances in which it will approve CISA maps. While the commenter stated that might be best done in guidance, they emphasized that HUD's final rule must define some ''high-level guardrails'' as well. The commenter suggested the following guardrails: (1) all maps must, at a minimum, be consistent with current CISA guidelines issued by the Water Resources Council,[34] National Climate Task Force, or equivalent Federal authority and (2) HUD should state clearly that it reserves the authority to deny or revoke approval of CISA maps for any reason.

Other commenters agreed that the proposed rule cannot be fully evaluated without CISA mapping being available for review and that it should not be implemented before the public can review the CISA mapping tools and provide comments. One commenter asked when the tools would be available to make nationwide determinations. Other commenters asked whether there will be a process for the public to refute the CISA maps.

One commenter emphasized the need to analyze granular property-specific data, including structure-specific identifications, first-floor height (FFH) assessments, and 1-meter digital elevation model data, in order to develop a reliable flood risk model. This commenter recommended that HUD use its co-chair position on the National Climate Task Force's FFRMS Science Subgroup to advocate for the addition of 'granular' as a necessary characteristic for ''best available data and science.''

One commenter requested that HUD develop its CISA maps with the following in mind to ensure they are developed properly: use currently established catastrophe models that have been recognized by State agencies and insurance commissions; do not extrapolate results; do not downscale data except through dynamic downscaling; do not rely on steady-state assumptions of the future; and display information on uncertainty and provide understandable outputs. The commenter emphasized that adoption by standard-setting organizations demonstrates model reliability as does peer-review. To that end, the commenter asked HUD to clarify what standard of peer-review would be effective and to follow up to confirm this standard has been met.

One commenter asked if CISA flood risk areas would be publicly available online. This commenter encouraged the development of a singular, publicly available website that reflects FFRMS approved methodologies.

Several commenters expressed concern about how HUD's CISA maps will be kept up to date. Commenters noted that these forward-looking maps should be required to be updated regularly as more data becomes available. Another commenter asked whether there will be a budget to make sure the CISA tool remains up to date.

One commenter requested HUD rename CISA to CISA–F to avoid confusion with another Federal tool called CISA for the Critical Infrastructure Act.

HUD Response: As described earlier in this preamble in section II.B., CISA is the preferred approach to define the FFRMS floodplain and HUD intends to require use of CISA where data is available and actionable. HUD agrees that it is premature to rely entirely on the CISA standard which is why HUD proposed CISA as the preferred of three methodologies to define the FFRMS floodplain. HUD recognizes that CISA data is not currently available nationwide via a Federal CISA implementation tool and therefore HUD has adjusted the language of this rule to allow, but not require, the use of State, local, or Tribal CISA data if they are available and actionable, as defined in § 55.7. HUD notes that while it cannot make funding explicitly available for this rule as no congressional appropriation has been made available to do so, many HUD programs do allow funding to be used for mitigation activities such as elevation and flood resilience efforts.

[34] HUD notes that these CISA guidelines are the same Guidelines discussed in the Background section of this preamble, available at *https://www.fema.gov/sites/default/files/documents/fema_implementing-guidelines-EO11988-13690_10082015.pdf.*

HUD made the proposed rule available for both public comment and comment through interagency review. Through the proposed rule, the public had opportunity to comment on, for example, whether the FFRMS floodplain should be defined using CISA where data is available. HUD received numerous comments on utilizing CISA to determine the FFRMS floodplain and other topics. As discussed more thoroughly elsewhere in this final rule, the public also had opportunity to comment on the use of CISA outside of this rulemaking through the guidelines.

HUD intends to release subregulatory guidance to help communities better understand the CISA process and how they can use acceptable tools to map the FFRMS floodplain. While HUD will not be releasing any CISA maps of its own, HUD does intend to accept maps, tools, or resources developed through Federal or local CISA data, when that data is available and actionable, as long as those maps, tools, and resources meet the requirements outlined in § 55.7(b), (c), and (f).

HUD disagrees that the proposed rule could not be evaluated or reviewed without CISA mapping being available. The concept of CISA and associated data is well established, as outlined in the FFRMS, the Guidelines, and the White House State of the Science Report, for instance.[35] The public has accordingly had opportunity to comment on CISA generally as well as its specific proposed use in topics addressed by this rule. The FFRMS and Guidelines, which were subject to public notice and comment, provided a method for considering CISA for coastal flood hazards that takes into account regional sea-level rise variability and service life of the project. Using CISA to define the FFRMS floodplain provides a forward-looking approach to flood risk management. Available and actionable CISA data is currently most readily available along the coasts in areas with the highest risk of flooding and, in accordance with E.O. 13690 and E.O. 11988, HUD is directed to utilize the best-available and actionable data to protect Federal investments. Where CISA data isn't available or actionable, HUD has provided additional acceptable processes to define the FFRMS floodplain including the 0.2-percent-annual-chance flood approach and the FVA.

[35] See *https://www.whitehouse.gov/wp-content/uploads/2023/03/Federal-Flood-Risk-Management-Standard-Climate-Informed-Science-Approach-CISA-State-of-the-Science-Report.pdf.*

HUD appreciates the commenter's thoughts regarding the need to analyze granular property-specific data and encourages grantees to utilize best-available data when complying with this rule. HUD notes that its outlined CISA approach for identifying the floodplain is consistent with the recommended approach from the Water Resources Council Guidelines.[36]

HUD disagrees that renaming CISA to CISA–F is necessary to avoid confusion and suggests that grantees use context to help differentiate between the acronyms.

d. 0.2-Annual-Chance-Flood Approach (500-Year Floodplain Approach)

Several commenters had concerns about limitations to the 0.2-percent-annual-chance flood approach. Several commenters pointed out that FEMA maps do not usually provide an elevation for the 0.2-percent-annual-chance floodplain. One commenter noted that FEMA does not regularly produce maps that incorporate wave modeling, which makes it difficult to plan projects and for residents to understand how regulations may impact their homes. This commenter encouraged HUD to work with FEMA to incorporate wave modeling in its 0.2-percent-annual-chance floodplain maps.

One commenter asked that HUD's final rule clearly define what 0.2-percent-annual-chance floodplain can be used, wondering whether its limits need to contain the structure, be within the subject property parcel, or be within 500 feet of the nearest structure. Several other commenters wondered what data would be used to determine the 0.2-percent-annual-chance floodplain.

One commenter asked if the addition of 2 or 3 feet to existing BFE to calculate a revised flood hazard area and flood elevation results in any changes to the extent of area considered seaward of the LiMWA. This commenter asked that the 0.2-percent-annual-chance flood method reflect the potential of the LiMWA to shift, as a result of sea level rise.

One commenter worried that the effects of using the 0.2-percent-annual-chance floodplain for properties with no known or previously occurring flood risk would reduce density and property values.

One commenter asked HUD to clarify if the 5/8-step process would be triggered by improvements in a 0.2-percent-annual-chance floodplain, and asked HUD to make the FFRMS guidance clear.

HUD Response: HUD appreciates the commenter's feedback regarding the limitations of the 0.2-percent-annual-chance flood approach. When the FEMA-mapped 0.2-percent-annual-chance floodplain is unavailable, or when, for critical actions, the FVA approach is higher, HUD would allow the FVA to be utilized.

In coastal areas, actionably accurate wave models can be difficult and expensive for jurisdictions to obtain. HUD would generally agree with the commenter that including wave modeling in coastal area flood maps is beneficial to accurately depicting flood risk which is why the CISA method is preferred. HUD will continue to work with its Federal partners to support their efforts toward increasing availability of mapping and modeling in coastal areas so that the best available data may be utilized for HUD projects.

For the 0.2-percent-annual-chance flood approach with non-critical actions, the final rule requires that the FEMA-mapped 0.2-percent-annual-chance floodplain must be utilized to determine if the structure is within the floodplain of concern. Additional technical assistance and guidance will be released alongside the rule to help grantees and practitioners make appropriate determinations for their projects and help them understand when the 8-step decision making process is required. As the 0.2-percent-annual-chance floodplain is not based on climate informed data but on current FEMA mapping, it would therefore be unable to account for sea level rise over time. Additionally, HUD notes that the rule does not change the FEMA-defined Base Flood Elevation.

The RIA found no evidence that the 0.2-percent-annual-chance flood approach would reduce property values and HUD expects any density loss to be intentional based on the goal of reducing flood risk.

e. Freeboard Value Approach

Several commenters encouraged HUD to adopt the FVA as the primary approach for defining the FFRMS floodplain. Several commenters recommended use of the FVA over CISA because CISA mapping is not available for public review and the public has not been provided adequate information to assess its impacts and implications. One commenter suggested the NEPA process cannot be completed correctly using CISA maps. One commenter concluded that given the uncertainties, relying on the FVA would be most likely to ensure

[36] HUD notes that these CISA guidelines are the same Guidelines discussed in the Background section of this preamble, available at *https://www.fema.gov/sites/default/files/documents/fema_implementing-guidelines-EO11988-13690_10082015.pdf.*

reliable and consistently documented building elevations.

Another commenter reasoned that FVA is the most accurate method of identifying flood risk and would be the most efficient use of government resources. Additionally, the commenter said FVA could be even more protective by adding two or three feet to the base flood elevation. This commenter urged HUD to consider further research into the FVA to compare the flood resiliency of HUD projects built to this increased standard to those that were not and into the possible benefits of using information in State Hazard Mitigation Plans.

Other commenters supported the FVA over the 0.2-percent-annual-chance flood approach because many sites do not have the 0.2-percent-annual-chance floodplain mapped and using the FVA across the board would result in a more consistent approach. Another commenter agreed that FVA is familiar to most stakeholders and supported its continued use given that it was HUD's previously selected method in 2016.

One commenter supported the inclusion of the horizontal floodplain when using the FVA.

Several commenters critiqued the requirement to add three feet to the BFE for critical actions, regardless of known or previous flood risk, and predicted this would lead to a reduction in density, higher costs, higher rents, and lower valuation of properties.

One commenter asked how the FVA method would account for high hazard areas that are subject to sea level rise and concurrent land subsidence.

HUD Response: HUD disagrees that the FVA should be utilized as the preferred approach to defining the FFRMS floodplain. While the FVA provides a beneficial fallback option when CISA and the 0.2-percent-annual-chance flood approach are unavailable, it does not account for sea level rise and the rising risk of flooding over time. The 0.2-percent-annual-chance flood approach is preferred to the FVA as it allows grantees to utilize existing tools to visually display the more protective horizontal extent of the floodplain. As stated earlier in section II.B., HUD requires that the FFRMS floodplain be defined using CISA where data is available and actionable, as it is the most scientifically accurate in providing impacts to the floodplain from climate change. As described in § 55.7, HUD considers CISA data to be available and actionable for a particular project where: (1) the data is included in a tool, resource, or other process developed or identified by a Federal agency or agencies to define the floodplain using CISA, and (2) HUD has adopted the particular tool, resource, or other process through a **Federal Register** notice for comment.

HUD disagrees that utilizing FVA as the preferred approach would be the most efficient use of government resources. HUD believes that the additional resilience provided by utilizing the hierarchy of CISA, then 0.2-percent-annual-chance flood approach, and finally FVA provides for a more resilient and effective use of resources than using a single approach across the board.

HUD appreciates the commenter's support for the inclusion of the added horizontal area under the FVA approach.

E.O. 13690 directs HUD to elevate critical actions at least three feet above freeboard value when using the FVA regardless of any previous flood risk at the site. While the FVA does not necessarily consider climate change because it is based on FEMA mapping of the BFE, a Federal tool for CISA is expected to be available in coastal and high-risk areas in FY24. As HUD's preferred methodology, CISA will better be able to account for sea level rise over time than other methodologies, even if they are more protective than current standards.

3. Other Alternative Approaches

One commenter suggested that HUD should consider looking to nearby areas that do have CISA resources available rather than solely relying on the two alternative approaches in the proposed rule.

One commenter requested certain public facilities such as fire and police stations, emergency medical facilities, and schools be given a heightened level of protection, and that HUD could look to more stringent standards for such structures from other entities.

One commenter asked HUD to reconsider using Advisory Base Flood Elevations (ABFE) to assess risk. ABFEs established after major flood events are often much higher than the 0.2-percent-annual-chance flood elevation, thus ABFE may result in situations where development would be required to elevate well above what the other proposed approaches would require. The commenter asked HUD to exclude ABFE from establishing elevations though, as it may not represent the true floodplain and could result in excessive fill or loss of opportunities to develop affordable housing.

One commenter noted that 0.2-percent-annual-chance floodplain elevation is not noted on FIRMS, which could lead to subjective elevation determinations by the technical experts required.

Another commenter recommended a new approach entirely, given that FEMA FIRM maps fail to account for forward-looking climate change and are not necessarily reliable with respect to historical flood risk either.

HUD Response: HUD agrees with the commenter and has revised the language of the rule at 24 CFR 55.7 to clarify that it permits a responsible entity to voluntarily define the FFRMS floodplain utilizing CISA when a State, Tribal, or local government has formally adopted, through code or other formal adoption measures, a tool, resource, or other written standards that provide data or other methods to identify the FFRMS floodplain using CISA for a particular project. HUD also notes that critical actions require a higher standard of protection, as their definition indicates, due to the potentially extreme impacts of flooding.

HUD believes that use of interim flood hazard data such as ABFEs is acceptable and that they can provide a realistic picture of the true floodplain when drawn by FEMA. While FEMA does not yet have comprehensive coverage of elevations on the 0.2-percent-annual-chance floodplain published maps, grantees will have the option of utilizing the FVA or calculating the 0.2-percent-annual-chance elevation when those elevations are unavailable from FEMA sources.

4. Questions About the Proposed CISA Approach

One commenter asked how maps would address the unpredictability of elevation sinking and if the maps would be adjusted yearly. Another commenter asked how HUD will decide what FIRM to go by and how a lender can be assured that the benchmark is accurate. This commenter also asked what happens when the FIRM is changed. Other commenters asked if flood studies would be required if there was insufficient information to establish FFRMS floodplains with one of the three approaches.

One commenter asked HUD to confirm whether the new rules apply to existing HUD-insured projects or federally funded projects seeking refinancing or acquisition and to detail all HUD Multifamily Housing programs that are expected to comply with this new guidance or any exceptions that make projects exempt or require compliance with these new rules.

HUD Response: HUD intends to provide additional guidance to grantees and practitioners to help them understand what options are available

when none of the three approaches have sufficient information to establish the FFRMS floodplain. Generally, HUD will rely on project-by-project technical assistance to help grantees find and utilize best available data to make their determinations. HUD believes that CISA tools will be regularly updated with best available climate and topographic data as outlined in the FFRMS CISA State of the Science Report.

HUD intends that the CISA provisions of the final rule will apply to any project funded by programs subject to part 55 review, including Multifamily FHA programs, in accordance with the compliance dates described in the Compliance Date section of this final rule.

B. Question #2: Whether HUD Should Define the FFRMS Floodplain for Non-Critical Actions as Whichever Is Lower Between the 0.2-Percent-Annual-Chance Floodplain or the Base Flood Elevation Plus Two Feet of Freeboard, Where CISA Resources Are Not Available

1. Support for HUD's Proposed Standard

Several commenters expressed support for whichever approach would offer the most protection when CISA is not available. Several of these commenters emphasized that the alternative proposed in Question #2 could significantly reduce flood resilience in some areas especially given that flood events are likely to become deeper and more frequent and because livelihoods, resident health, and safe homes are at stake. Another commenter said that any reduced short-term cost in using the less stringent approach would come at greater long-term expenses and would run counter to the risk management approach identified by the Government Accountability Office. The commenter also noted that models may underrate flood risk and the more protective approach is justified by the precautionary principle.

Another commenter urged HUD to consider collaboration with other agencies to gather data for critical actions in the proposed FFRMS floodplain.

HUD Response: HUD appreciates the feedback from commenters regarding the need for higher elevation standards and protections as flood events worsen due to climate change. The intent of HUD's preference for the CISA option is to be more proactive and protective as flood risks increase over time and to use the best science available at the time the project is considered. HUD believes that the process for using the 0.2-percent-annual-chance flood approach or the FVA when CISA is not available or actionable provides a protective and efficient process that is not only more likely to provide a more protective approach but also reduce administrative burden (*e.g.,* comparison between the 0.2-percent-annual-chance flood approach and FVA elevations).

For critical actions, where comparison between the 0.2-percent-annual-chance flood approach and the FVA +3 feet elevations is necessary, HUD believes the extra analysis is warranted to ensure more protection for those actions for which any risk of flooding is simply too great. HUD is also supportive of further collaboration with other agencies to analyze data on critical actions as it becomes available.

2. Support for the Lower Standard

Several commenters asked HUD to allow for the lower standard for non-critical actions. These commenters were concerned about incentivizing excessive fill in 0.2-percent-annual-chance floodplains.

Several commenters suggested that the FVA method should take preference over the 0.2-percent-annual-chance flood approach as it is easier to calculate. Some of these commenters went onto suggest that a site-specific flood study would be the best option.

HUD Response: HUD disagrees with commenters' feedback that lower standards should be used for non-critical actions. Since flood risks are increasing as a result of climate change and associated sea level rise, lowering the current regulatory standard on top of this increased risk would create an exponentially riskier environment for Federal investments and go against HUD's stated goals. HUD also disagrees that higher standards create incentive for fill as elevation does not necessarily require fill. In fact, the rule no longer provides an exemption for LOMR based on fill, further disincentivizing its use.

HUD disagrees that the FVA method is easier for grantees and practitioners to calculate than the 0.2-percent-annual-chance flood approach. The 0.2-percent-annual-chance floodplain is mapped by FEMA and where it is available for non-critical actions, grantees would not need to calculate anything. While HUD agrees that site-specific flood studies can be helpful, requiring them for all projects would be prohibitively expensive.

C. Question #3: Whether, and Under What Conditions, Part 55 Should Permit HUD or the Responsible Entity To Rely on the FFRMS Floodplain as Defined by Another Federal Agency

1. Support for Alignment With Other Agencies

Several commenters supported HUD using FFRMS boundaries established by other agencies to reduce redundancy in Federal oversight. These commenters also requested a process by which a stakeholder could request a reconsideration of HUD's floodplain boundaries.

Several commenters urged a cohesive and consistent Federal vision when there are multiple flood risk related efforts occurring simultaneously to avoid conflicting standards and potential noncompliance. One commenter noted the weaknesses inherent in not having a comprehensive nationwide approach to defining floodplains. This commenter encouraged HUD to include requirements for tracking the location and quantity of developments in floodplains as part of its 8-step decision making process. The commenter urged collaboration among Federal agencies to track and quantify the effectiveness of E.O. 11988 and E.O. 13690. Specifically, this commenter recommended that Federal agencies collaborate with the National Floodplain Functions Alliance.

One commenter suggested Federal agencies align their resilience and disaster response policies, including building codes and elevation requirements.

One commenter expressed support for a process whereby a project's lead Federal agency's implementation of FFRMS is sufficient for the entire project, as long as such approach looked at long-term risks.

More broadly, several commenters asked that HUD participate in collaboration with other agencies, affiliations, and interagency groups.

Several commenters stated that the Federal Interagency Floodplain Management Task Force (FIFM–TF) is an existing interagency body to facilitate collaboration and ensure that all agencies are using a forward-thinking, climate-informed approach. One commenter noted that HUD should rely on FIFM–TF policies, as long as its deliberations are more transparent and accessible to interested non-Federal stakeholders. This commenter suggested that since various Federal agencies have developed tools, data, and expertise, that collaboration would lead to more consistent CISA floodplain definition methods.

Several other commenters endorsed HUD's cooperation with the White House Flood Resilience Interagency Working Group. Some of these commenters said HUD should prioritize funding and interagency coordination, including continued participation in this working group. One commenter was concerned that the working group would not have enough resources available to accurately identify flood risks throughout the country. Another commenter asked who in this working group is preparing the CISA tools and whether they have any conflicts of interest between potential consultants working on these resources.

Several commenters urged HUD to rely on FEMA and its flood-risk data and to engage with FEMA to ensure complementary approaches as the agencies implement FFRMS through rulemaking. Another commenter emphasized that FEMA has spent billions of dollars on flood engineering studies and that adopting an alternative flood map dataset would waste previous Federal investments. The commenter went on to say that other entities, such as States, cities, and communities, have come to rely on FEMA's flood map data for various purposes. Another commenter noted that because FEMA is actively working to incorporate climate risk and future conditions into its data and mapping program, HUD should delay finalizing the proposed rule and continue to rely on FEMA's flood risk and mapping tools until its formal release of climate-informed flood risk data and flood maps.

One commenter supported coordination between HUD, FEMA, USACE, and other agencies to consistently articulate flood risks and best practices. This commenter reasoned that a comprehensive Federal narrative would allow for consistency and transparency for owners, local decision makers, and regulators as opposed to the current contradicting flood risk identification efforts.

One commenter suggested that HUD align its disaster recovery and mitigation construction standards with FEMA's Building Resilient Infrastructure and Communities and Public Assistance Programs, which have been successfully implemented for several years. The commenter said that adopting the flood provisions captured in modern building codes consistently across like programs would help the Federal government reduce complexity and increase programmatic efficiency.

One commenter asked that HUD share what it learns from developing CISA mapping tools with other Federal agencies.

HUD Response: HUD's outlined process in the rule requires the use of Federal CISA data where available and actionable, as described in § 55.7, or permits the voluntary use of formally adopted local CISA data, as described in § 55.7(f). A Federal agency tool is being developed by the Council on Environmental Quality (CEQ), the Office of Science and Technology Policy (OSTP), FEMA, NOAA, and HUD with input from the White House Flood Resilience Interagency Working Group and the FFRMS Science Subgroup. The Science Subgroup of the White House Flood Resilience Interagency Working Group has found that accounting for sea level rise in the coastal environment represents available and actionable data to help identify the CISA floodplain. The White House Flood Resilience Interagency Working Group has developed a job aid to help agencies identify the floodplain using the three approaches.[37] This job aid will help provide consistency of FFRMS application across the Federal Government.

Where Federal CISA data is not available and actionable, as provided in § 55.7, and grantees or practitioners use local, State, or Tribal CISA data, the 0.2-percent-annual-chance flood approach, and/or FVA, there may be some variation in the exact horizontal and vertical extents of the FFRMS floodplain depending on the approach that is utilized. HUD does not believe that these variations are likely to be significant and further believes that minor floodplain variation is worth the greater protection that the methodology in HUD's rule provides. HUD's rule does not define the boundary of the floodplain, only a methodology for determining where that boundary is. HUD does not intend to implement a formal process to contest the methodology used to define the floodplain at this time but will continue to monitor and make changes to policy, as necessary, to ensure effective determination of the FFRMS floodplain.

HUD agrees with the commenter that Federal disaster response policies, inclusive of their floodplain management policies, should be complementary and cohesive. As such, HUD drafted this rule to align with the E.O. 13690 guidance. Additionally, HUD appreciates the commenter's encouragement for HUD to continue cooperating with the White House Flood Resilience Interagency Working Group.

HUD's Federal partners are also engaging in rulemaking to update FFRMS floodplain requirements to comply with E.O. 13690. HUD cannot wait for these other agencies' rules and must act to protect its own investments which are otherwise at risk. However, each agency, including HUD, is developing these regulations with feedback provided through a required interagency review process which occurs prior to publication of any proposed and final rulemaking.

In cases where a Federal project is funded by multiple Federal funding sources, HUD plans to utilize the Unified Federal Review (UFR) to assist in the collaborative cross-agency/Department discussions to resolve compliance issues and ensure cohesion in project funding and goals. Additionally, HUD has procedures in place to adopt the environmental reviews of other Federal agencies to avoid unnecessary duplication of effort.

HUD supports its interagency partners and is always looking for new opportunities to work with other industry leaders in addition to other Federal agencies. While HUD agrees with the general sentiment behind adopting resilient building codes, HUD does not believe this rule is the proper place to include them.

2. Concerns With Relying on Other Agencies To Define the Floodplain

Several commenters expressed concerns regarding HUD relying on another agency's definition of FFRMS floodplains.

Several commenters said that HUD must ensure it is addressing resident health and safety as well as economic-related flood disaster relief in setting its floodplain determination, urging HUD to only rely on another agency's designation of FFRMS floodplain where that agency's methodology is at least as rigorous as HUD's; in other words, rely on whichever generates the highest elevation and most expansive horizontal floodplain. Another commenter similarly expressed concern for adopting other agencies' floodplain policies because they believe that HUD's proposed rule likely better protects wetlands. The commenter said that HUD should not rely on other Federal agencies at a time when the USACE's analysis for wetlands has changed through proposed rulemaking and the Supreme Court case *Sackett* v. *EPA*[38] regarding the definition of ''waters of the United States.''

Several commenters suggested that by not relying on FEMA's maps in its

[37] See *https://www.fema.gov/sites/default/files/documents/fema_ffrms-floodplain-determination-job-aid.pdf.*

[38] 598 U.S. 651 (2023).

proposed rule, HUD is indicating that FEMA's maps cannot be relied upon. Specifically, one commenter said the language that an interim or preliminary FEMA map could not be used if it is lower than the current FIRM or FIS indicates the FEMA maps cannot be relied upon for accurate flood risk data.

HUD Response: HUD agrees that it should avoid relying on another agency's definition of FFRMS floodplains. E.O. 13690 requires agencies to utilize one of the processes (CISA, 0.2-percent-annual-chance flood approach, FVA) based on best-available information and FIRMS from FEMA to define the FFRMS floodplain.

HUD is looking for the most scientifically prudent elevation based on available data that will provide protection of life, property, and the Federal investment. Using the CISA approach, HUD's preferred method, will likely result in the most protective elevation based on scientific data compared to other methods.

HUD believes that FIRMs provide an accurate point in time snapshot of flood risk. Unfortunately, these risks are continually changing and given the time horizon for FIRM updates they may be generally less accurate than HUD would prefer. The FFRMS approaches outlined in HUD's final rule allow for greater protection in the face of changing needs and uncertainty than a floodplain management approach solely based on FEMA's mapped BFE boundary.

D. Question #4: What Factors or Stakeholder Needs HUD Should Consider When Establishing an Effective Date for This Rule

1. Support for Extended Effective Date

Several commenters urged HUD to extend the effective date of implementation to at least one year after issuing this rule to avoid unforeseen expenses and delays for projects already in planning stages because development planning often begins years prior to land acquisition and formal planning processes. Of those commenters, several raised concerns that absent extension, developers would bear unequitable financial losses due to changes in land value purchased, revisions to plans, and resulting delays.

One commenter specifically urged HUD to include a grandfathering provision that would allow new Community Development Block Grants (CDBG) and HOME Investment Partnerships Program (HOME) awards, as well as FHA multi- and single family projects already under development and applications submitted prior to the effective date to proceed under current regulations. This commenter reasoned that if developers had to repeat the lengthy planning, platting, and government approval process for new development under changed regulations, they would be forced to engage in more consultation, negotiation, and compromise among all project stakeholders. This commenter added that the planning process for FHA insured projects is particularly lengthy.

Several commenters urged HUD to consider stakeholders' need to access the CISA maps prior to implementation, stating that it is impossible to examine implications of the rule absent sufficient review of the CISA method that the rule relies upon. Several commenters suggested that stakeholders needed at least one year to access the CISA maps prior to implementation. One commenter urged HUD to delay implementation until the CISA maps are available and approved and asked when HUD expected the tools will be made available.

Several other commenters went further, asking HUD to factor in time to engage industry stakeholders in developing the CISA mapping tool prior to implementing this rule. One commenter reasoned that improper development of this tool, or reliance on problematic data, could negatively impact industry stakeholders (*e.g.,* developers, insurance providers, floodplain mapping experts).

One commenter sought HUD's consideration that large public housing authorities need time to determine the impact of the regulation on costs of rehabilitation and repair, including a portfolio-wide review of covered properties and a building-by-building analysis. This commenter estimated that this review would take at least a year after final rule issuance.

One commenter suggested that HUD consider the potential positive result that proposed FHA mortgage requirements may incentivize communities to adopt 2-foot freeboard standards matching the HUD Minimum Property Standards, so that all development in special flood hazard areas will maintain qualification for FHA-insured mortgages. This commenter suggested that HUD extend the effective date for FHA mortgage requirements by one year to allow this commenter and other stakeholders to assist communities in updating their floodplain management codes. For all other aspects of the rule, this commenter urged HUD not to extend the effective date.

HUD Response: HUD appreciates the feedback from commenters regarding concerns over ongoing projects incurring unforeseen expenses and delays. As such, HUD is setting a delayed compliance period for the rule. Compliance with this final rule is required no later than 30 days after the rule becomes effective, except compliance with the amendments to 24 CFR part 200 is required for new construction where building permit applications are submitted on or after January 1, 2025, and compliance with the amendments to 24 CFR part 55 is similarly required no later than January 1, 2025, for FHA programs and programs subject to the MAP Guide, as more thoroughly described in the Compliance Date section of this final rule. This delayed compliance period will provide regulated entities time to come into compliance with this rule, including the portions of the rule implementing the Minimum Property Standards. HUD believes this delayed compliance period will allow ample time for project sponsors to prepare for any increased costs for compliance with the rule. Additionally, HUD notes that projects currently in development which have completed environmental reviews would not be required to backtrack for compliance.

HUD disagrees that stakeholders require access to CISA maps prior to implementation. After this rule becomes effective, CISA maps will not be used if they are not available and actionable. The three-tiered approach to define the FFRMS floodplain adopted by this rule will allow responsible entities to utilize the best available data and tools in their area to understand and mitigate their flood risk. As described in § 55.7, where State, Tribal, or local jurisdictions have already invested in data and modeling and created CISA data and tools, HUD permits the voluntary use of those tools if they result in an elevation that is at least as high as the lowest of (1) the 0.2-percent-annual-chance floodplain elevation; (2) the elevation that results from adding an additional two feet to the base flood elevation; or (3) the elevation required by paragraph (b) or (c) of § 55.7, if CISA data is available and actionable under paragraphs (b)(1) or (c)(1).

Federally assisted multifamily housing, especially housing for low-income and vulnerable populations, including the public housing portfolio, is currently in need of the additional flood mitigation and resilience requirements the rule requires. The rule will ensure that as properties undergo rehabilitation, flood mitigation and resilience will be incorporated. HUD does not believe it is appropriate or necessary to delay the implementation

of the part 55 update of this rule for additional study.

2. Support Implementing as Soon as Possible

Several commenters asked HUD to consider the urgent need to mitigate loss of properties and lives, along with the health and financial inequalities exacerbated by increasing flooding events, citing statistics on projected increases in flooding and disparate impacts of these events. Another commenter asserted that an effective date no later than January 1, 2025, would provide ample time for development stakeholders to prepare for implementation.

One commenter urged consideration of the number of HUD-supported new construction and substantial improvement projects that will or will not have enhanced resiliency and flood protections, depending on any delays to implementing this rule.

Another commenter suggested that HUD should consider the regulatory impact findings that the reduction in financial damages over the life of the project is greater than the one-time construction cost increases necessary for implementing the rule. This commentor also urged HUD to consider its knowledge of these impending requirements since at least 2015 as a factor supporting prompt implementation, with an effective date of no later than one year.

HUD's Response: After reviewing public comments, HUD has determined to provide a delayed compliance period to allow entities regulated by this rule a grace period to come into compliance with the revised requirements. Compliance with the amendments to part 200 of this rule is required for new construction where building permit applications are submitted on or after January 1, 2025. This delay is intended to provide home builders ample opportunity to adapt and prepare for the requirements of this rule, including the increased elevation standards. Compliance with the amendments to 24 CFR part 55 is similarly required no later than January 1, 2025, for FHA programs and programs subject to the MAP Guide, as more thoroughly described in the Compliance Date section of this final rule. Compliance with all other parts of this rule and for all other programs, except for those noted for parts 200 and 55, is required no later than 30 days after the rule becomes effective.

3. Additional Considerations

One commenter suggested that HUD consider the Supreme Court's decision on the Clean Water Act's definition of ''waters of the United States'' in *Sackett* v. *EPA.*

HUD's Response: HUD appreciates the feedback from commenters; however, HUD's definition of a wetland is unaffected by the Supreme Court's ruling in *Sackett vs. EPA* because HUD's wetlands definition originates from E.O. 11990, not from the Clean Water Act.

E. Question #5: Feedback on Exception Requiring the More Protective FVA Approach for Coastal Areas

Several commenters continued to recommend the most protective standard, supporting HUD's excepted use of the FVA standard in coastal areas. One commenter reasoned that wave action, sea level rise, land subsidence, warmer seas, and intensification of tropical storms/hurricanes compound uncertainty in coastal areas. Another commenter supported the higher standard to increase flood protection in areas where the mapped floodplain may not accurately reflect risks from wave action. Another commenter reasoned that the higher standard for coastal areas is necessary due to particular vulnerabilities of coastal communities to tidal flooding.

One commenter suggested that HUD's final rule should allow for the flexibility to use the most protective and up to date science in coastal regions or where higher quality data and analytics are available.

One commenter asked about HUD's plan for renovations in order to eventually have all projects in accordance with the new standards, and what the projected date is to achieve that plan. The commenter also asked, if there is no plan, whether one can be added to protect sustainability of coastal projects.

Other commenters opposed the higher standard for coastal areas, urging HUD to use a consistent approach in defining the FFRMS floodplain. These commenters suggested that compliance is stronger when the rules are consistently applied and easy to understand and recommended the FVA approach in all circumstances.

HUD's Response: HUD appreciates the commenters' preferences regarding the use of the most protective standard; however, HUD intends to retain the three-tiered decision making process to define the FFRMS floodplain as originally proposed to avoid complicating the process for builders and grantees. While HUD certainly encourages grantees to use the most protective approach where CISA isn't available or actionable, the Department believes that requiring grantees to look at both the FVA and 0.2-percent-annual-chance flood approach is unnecessary for noncritical actions. Instead, HUD will require review of both 0.2-percent-annual-chance flood approach and FVA to determine elevation heights only for critical actions. HUD believes that CISA tools will likely be available in coastal areas more quickly than inland locations and as such, should help to better determine the effects of sea level rise and wave heights for those structures.

HUD believes that a tiered approach with a preference for using CISA, where possible, before considering the 0.2-percent-annual-chance flood approach and/or FVA approaches, allows for the best outcome of both protectiveness and functionality for HUD grantees and recipients.

It should also be noted that the Federal funding action is the trigger for NEPA and part 55 compliance. Where a HUD-funded or -insured action is proposed, an environmental review meeting part 55 requirements is required. HUD will not be enforcing these requirements retroactively for projects with a completed environmental review.

F. Question #6: Feedback on Alternative Measures That May Help To Promote the Production and Availability of Affordable Housing in the Near-Term While Still Promoting Flood Resilience

1. Arguments That HUD's Proposed Rule Will Impede Affordability and Housing Supply

Several commenters raised concerns that development restrictions and/or increased costs to comply with proposed requirements would chill interest and ability to develop, operate, or rehabilitate affordable housing, resulting in higher rents and housing costs, limited ability to borrow, and/or unattainable loans. Additionally, several commenters stated that increased compliance costs will result in borrowers deferring or foregoing repairs and upgrades to existing affordable housing.

One commenter disagreed with HUD's projected construction costs, asserting that HUD relied upon an outdated 2013 FEMA study, which fails to account for inflated input prices, supply chain challenges, and labor challenges. This commenter also questioned HUD's certification that there is no significant economic impact on small entities, citing that 88 percent of homebuilders and specialty contract firms are self-employed independent contractors. The commenter provided its own survey of builders, finding that elevating single-

family home to two feet above BFE would add $5-$10 thousand dollars to cost of construction; and costs would be even higher where builders prefer slab foundations due to humidity, which are more expensive to elevate than homes on piers. Further, this commenter conducted the following analysis of the impacts of cost increases on homeowners and renters: a $1,000 increase in median home price would price 140,436 households out of the market; a $1,000 rent increase per unit would price out an additional 32,289 renters.

Several commenters explained that elevation requirements would cause increased transportation costs for soil import from certified fill sites and earthwork and compacting costs of the additional fill.

Several commenters specifically identified the requirement to maintain flood insurance as causing additional operating costs, which will be passed along to residents in the form of higher rents and housing costs. Several commenters stated that it is unlikely that insurance costs for homeowners or multifamily owners will decrease sufficiently to offset the increased construction costs, asserting that HUD did not provide evidence that insurance costs will decline.

One commenter stated that limiting the current streamlined 203(k) loan to $35,000 in renovations means that it may not be a lending option for borrowers mandated to raise substantially damaged properties to BFE +2 feet.

Several commenters noted that affordable multifamily building and rehabilitation projects may be deferred, scaled back, or foregone where increased costs cannot be offset by increased rent, preventing delivery of needed housing supply. Several of these commenters reasoned that there is a direct correlation between Federal housing policies impacting housing supply and affordability and homebuilding stakeholders' willingness to create affordable housing supply.

One commenter noted that underproduction of housing has translated into higher housing costs, resulting in a decline in the number of affordable units currently available. This commenter outlined difficulties facing housing providers—narrow margins, ongoing labor and material challenges, elevated regulatory costs—and cited recent surveys indicating that 79 percent of developers reported construction delays, with almost half citing project infeasibility as the cause.

One commenter stated that the proposed rule's floodplain expansion will reduce opportunities to develop HUD projects in low-lying areas and thus reduce housing for low-income families, who are in turn less likely to be able to afford relocation.

HUD Response: HUD appreciates the commenters' feedback about their concerns that additional elevation requirements could increase costs and chill investment in future housing. HUD acknowledges that the additional elevation requirements from the increased elevation standards proposed to the Minimum Property Standards and the increased regulatory footprint proposed in the part 55 update could have additional costs associated with them. In the RIA, HUD found that the increase in construction costs for new residential structures of elevating an additional 2 feet above BFE would average between 0.3 and 4.8 percent of the building cost. HUD contends that the benefits of protection provided by these mitigations are greater than the cost of compliance. In fact, the RIA shows that the lower bound for losses avoided based on the updated part 55 provides more than $50 million in benefits even using the higher 7 percent discount rate. Federal investment in the construction of multifamily and/or public housing in riskier areas prone to flooding does not increase the availability of safe affordable housing units. It is HUD's goal to disincentivize continued Federal investment in high-risk flood-prone areas.

Short term market volatility in prices and labor is a poor indicator for regulatory decisions and those factors are instead looked at in aggregate over longer study periods. HUD reviewed the best available studies and stands by the construction costs and potential impacts on builders of all sizes as outlined in the RIA.

HUD strongly disagrees that elevation requirements would cause any change in transportation costs for fill. In its rule, HUD is not mandating how elevation is achieved; therefore, grantees are free to utilize methods of elevation that do not involve fill. Additionally, with the removal of the exemption for LOMRs based on fill, HUD is actively discouraging its use as a method for elevation.

With this rule, HUD is not changing its requirements for maintaining flood insurance, which are mandated by statute. Therefore, HUD disagrees that utilizing existing requirements will increase operating costs. HUD grantees have also always had the ability to extend flood insurance requirements beyond those established as the minimum by HUD. Additionally, HUD notes that HUD's encouragement for the purchase of flood insurance outside the 1-percent-annual-chance floodplain is not a requirement.

HUD has decided to remove the elevation requirement for substantial improvement under the Minimum Property Standards to avoid adversely impacting homeowners renovating existing single-family homes. While HUD appreciates the commenter's feedback regarding 203(k) loans, Standard 203(k) financing allows a homeowner to finance improvements with an insured mortgage that may be based on a loan-to-value ratio using 110 percent of after improved value of the property. Regarding Limited 203(k), on November 29, 2023, HUD published a draft Mortgagee Letter (ML), *Revisions to increase the Maximum Rehabilitation Costs for Limited 203(k), Rehabilitation Period for both Standard and Limited 203(k), and Consultant Fees Schedule for the 203(k) Rehabilitation Mortgage Insurance Program (Section 203(k) Program),* for feedback on the FHA's Office of Single Family Housing Drafting Table. The ML proposes to expand the rehabilitation costs for Limited 203(k) from $35,000 to $50,000 and to $75,000 for high cost areas.[39]

2. Arguments That HUD's Proposed Rule Will Improve Housing Affordability

Several commenters asserted that property resilience investments are necessary to increase affordable housing at individual and/or government-wide levels.

Several commenters suggested that reduced property damage and broader socio-economic costs (*e.g.,* displacement) created by this rule outweigh potentially increased construction costs for projects in flood-prone areas, in turn increasing housing affordability. One commenter cited evidence that the number of affordable housing units at risk from coastal floods and sea level rise is expected to triple over the next 30 years.

Several commenters stated that it is incorrect to measure the costs of flood resilience requirements solely by increased construction costs/home prices because the cost of homeownership also includes costs to live in, maintain, and insure a home over time, especially homes subject to recurrent natural disasters that may become uninhabitable (and the broader cost of communities becoming uninhabitable).

[39] The draft ML is available at *https://www.hud.gov/program_offices/housing/sfh/SFH_policy_drafts.*

Another commenter cited evidence that the savings benefits of building to modern building codes come without negatively impacting housing affordability, stating that no peer reviewed research finds otherwise. This commenter cited findings that insurance savings from meeting mitigation requirements can reduce homeowners' net monthly mortgage and flood insurance costs by at least 5 percent, balanced against about half a percentage point increase in home purchase price for improvements to model resilience codes in an area affected by riverine floods.

Another commenter suggested that the proposed rule mitigates increased construction costs through its identification of practicable alternatives and provision of technical assistance to help recipients comply with new standards.

One commenter argued that disaster resiliency standards will lessen reliance on HUD to rebuild and replace community assets damaged by natural disasters, allowing HUD to prioritize programs that increase the stock of affordable housing and availability of mortgage insurance. This commenter provided examples of post-flood closures of multifamily units precipitating negative shocks to local housing markets.

Several commenters pointed to jurisdictions and programs that already require greater elevation standards and requirements than HUD as demonstrating that stronger standards are feasible and cost-effective.

One commenter urged that the demonstrated long-term financial benefits of flood adaptation (citing a 6:1 benefit-cost ratio for HUD- and FEMA-supported mitigation measures) should be extended to affordable housing residents.

Another commenter supported measuring/scoring property-level risks across the spectrum of environmental hazards, providing government and private stakeholders with insight to balance the costs and benefits of adding finely tuned/tailored resiliency measures to building codes.

HUD's Response: HUD appreciates the commenter's sentiment that property resilience investment from the Federal level is necessary to increase affordable housing. HUD agrees that the reduced property damage and broader socioeconomic benefits created by this rule outweigh the additional cost of compliance for flood-prone areas. This is even more important in areas that may be affected by climate change.

HUD appreciates commenters' feedback regarding the measurement of the cost of flood resilience. While HUD agrees that the cost of a community becoming uninhabitable over time would have more devastating effects than simply more expensive housing, it is unfortunately difficult to quantify those consequences outside of their direct economic impact. Generally, HUD agrees with the commenter's sentiment that the savings benefits of modern building codes on housing outweigh any impacts on housing affordability. HUD has previously and will continue to help grantees review practicable alternatives when project costs are too high to build due to elevation requirements.

HUD generally agrees with the commenter's feedback that the increased resilience standards should help avoid damages from future flood disasters and thus increase the longevity of new affordable housing. HUD appreciates its local partners that have already demonstrated the effectiveness and feasibility of higher standards in their communities.

3. Suggested Revisions Commenters Believe Will Help Promote Affordable Housing

One commenter suggested that HUD amend the rule to provide greater financial flexibility to design and construction firms by quantifying design/construction-related costs to achieve the FFRMS as deferred maintenance instead of substantial improvements.

Another commenter suggested that HUD proactively target financial and technical assistance to support low-income and historically disadvantaged communities, stating that opportunities recently codified by the Community Disaster Resilience Zones Act, Public Law No. 117–225 could be instrumental.

One commenter urged HUD to increase per unit maximums and provide waivers where necessary (*i.e.,* match requirements) to ensure that communities in which the entire buildable area is within newly designated floodplains do not confront such high costs as to effectively cut off HUD funding.

One commenter urged HUD to revise the flood elevation measurement for manufactured homes to be consistent with the site-built homes measurement, to ensure that manufactured homes remain cost effective. This commenter reasoned that expanding the supply of manufactured housing is a crucial component of preserving affordable housing and that a large number of manufactured homes are located on floodplains.

HUD's Response: HUD believes that for the purposes of compliance with floodplain mitigation requirements under part 55, rehabilitation needs to be considered substantial improvement when the costs are more than 50 percent of the value of the structure and/or they include the expansion of units by more than 20 percent. HUD notes that simply because a project is considered a substantial improvement does not mean that that project cannot move forward under the current part 55 requirements. Part 55 simply adds mitigation requirements to ensure that the overall structure is more resilient. Even in communities where large swaths of the buildable area fall into the regulatory floodplain of concern, the requirements do not prohibit building; they require mitigation to ensure new construction is safe. HUD notes that § 55.21 also provides an alternative process for existing nonconforming sites meeting specific thresholds for protectiveness to continue to receive support and avoid cutting off existing communities from Federal funding.

HUD agrees with the commenter's feedback that HUD funding programs and technical assistance should benefit low-income and historically disadvantaged communities. Such benefits are explicit requirements for many HUD funding programs and are included in Goals 1 and 2 of HUD's Strategic Plan: Support Underserved Communities and Ensure Access to and Increase the Production of Affordable Housing.

HUD agrees with the commenter about consistent regulations and HUD has and will continue to require that manufactured housing requirements be consistent with those for stick-built homes with regards to part 55 elevation requirements. Under part 55, new siting and substantial improvement of manufactured housing units (MHUs) are considered the same as new construction and substantial improvement for stick-built homes and therefore subject to the part 55 elevation requirements. To clarify this policy, HUD has revised the rule language to reference MHUs in the definitions for new construction and substantial improvement.

Further, for both manufactured homes and stick-built homes subject to part 55, to determine the lowest floor, HUD looks to FEMA's regulations in 44 CFR 59.1 and FEMA's Elevation Certificate guidance or other applicable current FEMA guidance. For manufactured homes in A Zones, FEMA recommends measurement of MHU elevation from the I-beam as a best practice. HUD recommends following FEMA best practice where feasible. For manufactured homes in coastal high

hazard areas (Zone V), FEMA requires measurement of MHU elevation from the bottom of the lowest horizontal structural member (*e.g.,* the I-beam).

It is important to note that FHA-insured single family housing is not subject to part 55 and that FHA-insured manufactured housing is not subject to part 55 or to the 24 CFR 200.926d elevation standards under this final rule. Eligibility requirements, including elevation standards, for FHA-insured manufactured housing can be found at 24 CFR part 3285: Manufactured Home Installation Standards and 24 CFR 203.43f: Eligibility of Mortgages Covering Manufactured Homes, as applicable, which are outside the scope of this rulemaking. HUD understands that the part 55 elevation requirements for MHUs differing from the FHA insured MHU requirements may lead to confusion where HUD programs subject to part 55 are installing MHUs. To address this, HUD intends to release guidance and technical assistance material focused on these MHU requirements which should help project sponsors and responsible entities ensure compliant programs.

HUD agrees with commenters that wish to minimize the disruption to the delivery of affordable housing. As such, after reviewing public comments, HUD has determined to provide a delayed compliance period to allow entities regulated by this rule a grace period to come into compliance with the revised requirements. Compliance with the amendments to part 200 of this rule, including the update to the Minimum Property Standards, is required for new construction where building permit applications are submitted on or after January 1, 2025. This delay is intended to allow home builders and developers ample opportunity to adapt and prepare for the requirements of this rule. For FHA programs and programs subject to the MAP Guide, compliance with the amendments to 24 CFR part 55 is similarly required no later than January 1, 2025, as more thoroughly described in the Compliance Date section of this rule. Compliance with all other parts of this rule and for all other programs, except for those noted for parts 200 and 55, is required no later than 30 days after the rule becomes effective.

4. Additional Suggestions To Promote Resilient and Affordable Housing

Several commenters urged HUD to pair efforts to make floodplain housing more resilient with a focus on affordable housing development outside of floodplains and solving how to accommodate growing housing need as floodplain housing becomes increasingly uninhabitable. One commenter reasoned that focusing affordable housing development outside floodplains and wetlands will counter longtime exclusionary zoning practices and direct scarce financial resources to building affordable housing instead of mitigation activities. However, this commenter stated that HUD should still fund rehabilitation of existing affordable housing in floodplains through programs like Community Development Block Grants for Disaster Recovery (CDBG–DR) to prevent displacement. This commenter outlined their view of three root causes of the current shortage of affordable housing—Congress consistently underfunding housing subsidies; Congress's decade's long divestment in existing public housing; and a severe lack of disaster housing resources and the use of those limited funds for non-housing costs, and those funds disproportionately benefit homeowners over renters. Another commenter suggested that HUD proactively fund buyouts with relocation assistance for persons living at properties that have experienced severe repetitive losses.

One commenter urged HUD to take the following additional measures to promote production and availability of affordable housing: (1) require HUD CDBG–DR and Community Development Block Grants for Mitigation (CDBG–MIT) grantees to rebuild public and affordable housing on a one-for-one basis, deeply affordable in lower-risk areas and in a manner that affirmatively furthers fair housing (AFFH); (2) ensure that the right to return to communities is not conditioned on returning to high-risk area; (3) ensure that grantees are using funding to redress historical disinvestment in infrastructure—including flood protection infrastructure—in low-income communities and communities of color; (4) carry out Department AFFH obligations and ensure that HUD holds grantees accountable for complying with civil rights obligations on which Federal funding is conditioned; and (5) ensure that subsidies, including Housing Assistance Payments (HAP) contracts, can be easily transferred to new sites and require a new assessment before HAP contracts are renewed following a flooding event.

Another commenter urged HUD to consider ways to expedite the regulatory process for affordable housing projects, while ensuring they follow proposed requirements.

HUD's Response: HUD appreciates the commenters' feedback regarding making floodplain housing more resilient by encouraging development outside the floodplain where feasible. The 8-step decision making process does require project sponsors to consider alternatives to any development plans in the floodplain. HUD encourages this alternatives analysis to consider other more resilient sites located outside the floodplain.

While HUD does not consider this rulemaking the appropriate place to consider changes to disaster assistance funding or other HUD programs, HUD appreciates the commenters' enthusiasm for Federal assistance directed towards increasing affordable and resilient housing. HUD notes that individual HUD programs may introduce program specific guidance or policy to more efficiently implement FFRMS requirements.

F. Question #7: Feedback on the Proposed FHA Single Family Minimum Property Standards

A discussion of the comments received regarding the FHA single family Minimum Property Standards can be found in this Public Comments section of this final rule in the subsection titled *Minimum Property Standards for 1–4 unit residential structures.*

G. Question #8: Whether Provisions of the Proposed Rule Will Redress, Perpetuate, or Create Any Disproportionate Adverse Impact Against Any Group Based on Race, National Origin, Color, Religion, Sex, Familial Status, or Disability, as Well as How HUD Can Further Incorporate Equity Considerations Into This Proposed Rule To Help HUD Meet Its Affordable Housing and Community Development Mission

1. Proposed Rule Promotes Equity

Several commenters stated that the proposed rule's blended climate and equity lens will contribute to redressing disproportionate adverse impacts faced by protected classes; and that allowing communities of color and low-income communities to endure elevated flood risk would perpetuate systemic inequalities.

Several commenters specifically supported requiring inclusion of environmental justice public engagement in the 8-step decision making process. Several commenters added support for HUD's plan to issue policy guidance on environmental justice.

Several commenters stated that replacing the misleading 1-percent-annual-chance flood approach with the CISA approach will ensure more

accurate accounting for hazard risks to federally assisted housing. One commenter explained that this is essential to promote wealth retention in Black, Hispanic, Indigenous, and low-income communities harmed by centuries of inequitable resource allocation and exposure to natural and artificial hazards, including heightened exposure to hazardous flooding and inequitable distribution of disaster aid.

HUD Response: HUD appreciates the commenter's feedback regarding climate and equity. It is the Department's goal to fully implement the goals and objectives of E.O. 14096, including to identify and address disproportionate and adverse human health or environmental effects of the Department's programs, policies, and activities on communities with environmental justice concerns, while also working to be more protective and promote resiliency to flooding. HUD agrees with the commenter's sentiment that CISA should help to better account for and reduce hazard risks to federally assisted housing. HUD also agrees that housing is an essential component to generational wealth building and that ensuring its resilience in the face of flooding helps communities build into the future.

2. Proposed Rule Perpetuates or Creates Disproportionate Adverse Impacts on Protected Classes

a. Inequities Perpetuated by Continued Development in High-Risk Areas

Several commenters raised concerns with provisions of the proposed rule that they assert would perpetuate or create disproportionate adverse impacts on protected classes, citing evidence showing the following: a disproportionately high percentage of low-income, minority, and other communities that are vulnerable to flooding live in high-risk areas; communities of color face disparate adverse impacts of flooding (both in rate of flooding and damage caused by flooding), as well as face challenges with access to post-disaster resources and rehabilitation. One commenter cited evidence that flood risk will increase by 26 percent by midcentury and would be disproportionately high for Black communities, with population growth in flood-prone areas accounting for 75 percent of that increased risk (and 19 percent caused by climate-related flood impacts).

Several commenters asserted that even with the administrative steps of § 55.20, the exemptions in part 55 allowing continued housing development in high-risk areas will perpetuate and create disproportionate adverse impacts on several protected classes of people, especially considering that its primary application is subsidized housing units. Several commenters noted that along with placing residents in danger, this will cause HUD and other public entities to spend limited resources on disaster recovery for all citizens, taking away from investments in affordable housing and programs to redress historical disparities. Several commenters cited FEMA risk data that 32 percent of federally assisted housing stock (1.5 million housing units) is at high risk of negative impact for natural hazards, compared to 24 percent of market rent homes and 14 percent of owner-occupied homes. These commenters noted that underestimates in FEMA's 1-percent-annual-chance flood hazard measurements mean that many more federally assisted homes are at risk, which supports the need for the new FFRMS standard to better assess risk. Another commenter presented evidence on how maladaptation measures—such as new infrastructure that cannot be improved without significant investment—entrench inequities.

One commenter explained that racial disparities in flood vulnerability are a direct result of local, State, and Federal exclusionary policies and practices, perpetuated by this rule. This commenter asked HUD to revise the 8-step decision making process to directly account for historical patterns and practices of affordable housing placement. This commenter caveated their response by adding that HUD must continue to provide funding to rehabilitate and improve the resilience of existing subsidized units in high-risk areas and honor residents' right to return to prevent post-disaster displacement.

This commenter also emphasized that households with low incomes are negatively impacted by flooding even if all mitigation and floodproofing measures are taken. The commenter explained that flooding damage takes a variety of forms such as the destruction of vehicles and personal property, toxins spread by floodwaters, and disruption of employment or childcare. As such, people with low incomes may experience significant negative impacts from flooding that are not related to damage to a housing unit. The commenter added that FEMA is shifting resources away from ''small disasters,'' reducing the resources available for replacing personal property, and that residents of homes built in FFRMS floodplains will continue to be significantly impacted even with the floodproofing and mitigation steps outlined in this proposed rule.

Several commenters asserted the alternative processing for existing nonconforming sites under § 55.21 will perpetuate or exacerbate inequalities. One commenter explained that exceptions are typically granted based on the condition under § 55.21(a)(1) that it's not ''practicable to transfer . . . under existing program rules, financial limitations, and site availability,'' by relying on historical discriminatory policies and practices that resulted in the disproportionately high rates of affordable housing in the high-risk locations. Providing two examples of HUD supporting development repair in unsafe areas, this commenter argued that HUD cannot excuse its obligation to redress discriminatory government policies and practices because those policies have, for example, increased property values in lower risk areas. Another commenter asserted that HUD failed to support the existing non-conforming sites with evidence that the floodway and adjacent areas will be safe over the next 20–40 years, also the relevant term of years for several listed forms of HUD assistance. This commenter referenced four HUD Inspector General reports finding problems with HUD's assessment of environmental and health risks. This commenter posed the following questions to HUD as important considerations in understanding the impacts of this provision on protected classes:

(1) Did HUD perform analysis on potential complete impacts related to floodways?

(2) How will the floodway analysis occur on an individual site basis?

(3) How is HUD projecting floodway expansion related to increased atmospheric water vapor over coming decades?

(4) How will HUD use climate science to project floodways' potential instability?

(5) How will HUD's site analysis consider climate-induced increase in pluvial flooding?

(6) How will HUD's site analysis consider potential sea level and associated groundwater rise?

(7) What is the universe of these floodway projects?

(8) What is HUD's estimate of how many HUD-assisted projects have buildings in floodways?

(9) How many similar projects has HUD found with floodway impacts?

(10) What racial equity and environmental justice considerations did HUD account for in drafting this provision?

(11) How will racial equity and environmental justice analysis apply to individual sites?

Another commenter asked HUD to address its decision to allow public housing residents to stay in or near a floodway in a rule acknowledging the dangerous and increasing impacts of climate change.

Another commenter added that stronger protections would lessen reliance on HUD to rebuild and replace community assets damaged by natural disasters, which currently divert funds away from programs targeting low-income families, aging populations, and persons with disabilities.

HUD Response: HUD appreciates the commenter's concern that many low-income communities and communities of color live in higher risk areas in and around floodplains. HUD believes that this rule supports a greater resilience within these communities to flooding and other related disasters, thus avoiding loss of services during disasters and any disparate adverse impacts. Resilient infrastructure helps to counteract entrenched inequalities by providing communities with resilient services through floods. HUD believes that a policy which bars development in the FFRMS floodplain would be too restrictive and have a significant negative impact on affordable housing availability. By allowing limited development and requiring flood risk mitigation equitably across the FFRMS floodplain through this rule, HUD believes substantial risk reduction can occur without substantial impact on housing affordability for all communities across the Nation who face flood risk. HUD agrees with commenters that the FFRMS standard is needed to better assess risk for Federal projects.

Separate from this rulemaking, a critical part of HUD's mission is to fully implement the Fair Housing Act, which not only prohibits discrimination but also directs HUD to ensure that the Department and its program participants proactively take meaningful actions to overcome patterns of segregation, promote fair housing choice, eliminate disparities in housing-related opportunities, and foster inclusive communities that are free from discrimination. In keeping with this mission, HUD also notes that under the new rule, § 55.20(b)(4) requires that any activity in a community with environmental justice concerns must coordinate its consultation and decision making from §§ 50.4(l) and 58.5(j). HUD disagrees that this rule perpetuates exclusionary policy that exacerbates racial disparities in vulnerable communities. HUD is working on fully implementing the goals of E.O. 14096 on revitalizing the nation's commitment to addressing environmental justice, which includes implementing practices that address or prevent exacerbating disparities in vulnerable or other affected local communities, along with other relevant E.O.s. In keeping with the goals of E.O. 14096, this rule will align other HUD programs with existing disaster recovery program requirements for elevation and will continue to allow projects to proceed in the floodplain so long as mitigation is incorporated into the project scope. HUD believes this alignment will help to increase the resiliency of vulnerable communities in high-risk areas.

HUD appreciates that no flood mitigation except for buyouts is entirely safe over time and that some households with low incomes can be negatively impacted despite the best mitigation efforts. The RIA considered the benefits of losses avoided from flooding. While HUD maintains no authority over FEMA's disaster assistance efforts, it is the objective of HUD for this rule to significantly improve resilience of newly built structures in the floodplain.

HUD appreciates the specific questions provided by commenters regarding implementation of the rule and will work to address these questions through future guidance. Regarding increases in atmospheric vapor and the expansion of the floodway, HUD relies on FEMA to determine and define the floodway as part of its FIRM process. HUD also intends to continue to rely on CISA data as it becomes more readily available. Over the next 20–40 years, HUD anticipates a significant development in flood resilience data, which will bolster the availability of CISA data nationwide. This in turn will result in better flood resilience outcomes. HUD notes that the rule's RIA contains equity and environmental justice analyses.

b. Concerns With the Public Notice and Community Engagement Requirements

Several commenters urged HUD to go beyond proposed public engagement and notice requirements in the proposed rule, mandating more accessible and transparent public notice to prospective buyers and renters in floodplains; community-led planning and decision making; and full accounting for long-term and indirect risks. These commenters reiterated that community engagement in planning and the floodplain hazard notice is a critical requirement that will allow for informed decisions but identified issues that they believe will perpetuate inequalities.

Several commenters stated the proposed 8-step decision making process and transparency requirements only account for short-term, direct damages of flooding and must be improved to account for long-term and indirect safety risks to those considering living in flood-prone areas. One commenter specified several indirect harms of flood events that have a disproportionate impact on marginalized communities not addressed by the proposed mitigation and floodproofing measures—toxins spread through floodwaters; disruption of employment, education, healthcare access; and infrastructure damage. More broadly, another commenter urged HUD to specifically account for the holistic cost of homeownership/rental value over the life of a home in assessing economic impact of requirements and disparate burdens throughout this rule, including the cost to live in, maintain, and insure a home over time, especially homes subject to recurrent natural disasters that may become uninhabitable. This commenter cited several sources finding that race, ethnicity, physical disability, and age are factors that significantly impact disaster vulnerabilities.

Another commenter urged HUD to amend §§ 55.20(f)(2)(iii) and 55.4 to ensure that environmental justice reviews require both public participation and a substantive analysis of the proposed action to ensure it does not overly burden existing communities. This commenter opposed exempting environmental justice outreach when data or mapping does not identify a particular community of concern. This commenter asserted that such flexibility: (1) incentivizes developers to save money by foregoing robust environmental justice review alongside communities historically underrepresented by land use decisions; and (2) shifts the burden onto community members. Specifically, this commenter urged HUD to delete the parenthetical ''if conducted'' from Step 6 under § 55.20(f)(2)(iii). This commenter stated that this proposed revision aligns with other HUD guidance, such as the environmental justice worksheet.

This commenter also asked HUD to amend § 55.4, § 50.23, § 58.43, or § 58.59 by adopting language access requirements from the voting rights context to ensure that immigrant and other non-English speaking communities have access to hazard notifications and can participate in community engagement. This commenter recommended that HUD model requirements after Section 203 of

the Voting Rights Act, stating that materials must be provided in alternative languages where, according to the U.S. census, citizens of voting age: are more than 10,000, or more than five percent of all voting age citizens, or on an Indian reservation, are more than five percent of all reservation residents; and the illiteracy rate of the group is higher than the national illiteracy rate. Additionally, this commenter urged HUD to amend § 55.20(b)(2) to allow at least a sixty (60) calendar day comment period, which this commenter stated will create no additional delay or economic harm, while providing necessary opportunity for public awareness.

Another commenter asked HUD to add notification requirements for actions involving repossession, receivership, foreclosures, and similar property acquisitions; and where issuance of rental subsidies is not associated with a project. This commenter reasoned that that HUD-associated foreclosed homes are often resold with scant information.

Another commenter urged HUD to strengthen the flood risk management and project design criteria in the following ways: (1) mandate proactive outreach to affected communities; (2) require both early resident and community leader engagement and engagement carried forward throughout project design and implementation; and (3) specify that communities' lived experiences—regarding community priorities, intended uses, flood susceptibility, and population specific concerns—are given equal weight as technical modeling in flood mitigation options assessments. This commenter reasoned that co-producing these assessments and planning processes will make residents more likely to support projects and help to address any obstacles, improve community understanding of flood risks and how they can individually prepare, and reinforce a sense of community.

Another commenter encouraged HUD to include additional flood insurance resources for those who may have difficulty understanding these insurance policies.

Another commenter urged HUD to amend §§ 55.20(f)(2)(iii) and 55.4 by incorporating other agencies' guidance (*e.g.,* the EPA Legal Tools to Advance Environmental Justice) and to define the substantive analysis necessary in an environmental justice review. For example, this commenter stated that environmental justice reviews must also require mitigation or an alternatives analysis if a project will have harmful impacts on the community. This commenter also stated that review must account not only for flood risk, but also for the intersecting and cumulative risks from all environmental hazards and disparate impacts, including discriminatory zoning, hazardous uses, disinvestment in infrastructure, and housing discrimination.

Several commenters stated that while allowing online posting improves accessibility in some ways, it still puts the onus on residents to identify projects that may affect them.

One commenter asked how HUD plans to remove barriers that low-income and protected stakeholders face that may make it more difficult for them to participate stakeholder meetings.

HUD Response: HUD appreciates the commenters' sentiment for greater accessibility and transparency for public notices to prospective buyers and renters in floodplains. HUD agrees that greater notification standards can allow for buyers and renters to better account for those risks when considering flood insurance. Additionally, HUD agrees that greater community engagement in planning and floodplain hazard notices is a critical component of the 8-step decision making process. HUD believes that the increased notification requirements for buyers and renters, along with more acceptable methods of public noticing for the 8-step decision making process found in the rule, will create the greater transparency and accessibility of vital floodplain information without creating undue regulatory burdens on already limited funding for projects.

HUD believes that Step 4 of the 8-step decision making process specifically requires responsible entities to look at direct and indirect impacts of building their project in the floodplain or wetland and that the requirements in the rule and the existing 8-step decision making process are not limited to the short-term impacts of living in flood-prone areas.

While HUD appreciates the comments on economic impacts associated with living in the floodplain, it would be inappropriate under the rule for HUD to address the holistic cost of home ownership in areas prone to natural disasters. There are innumerable potential influences of the holistic costs and indirect safety risks associated with homeownership/renting and it is impossible to account for all possible factors. HUD feels strongly that the RIA analyzes all relevant costs and benefits associated with this rulemaking. HUD appreciates the commenters' feedback that environmental justice reviews should be included more broadly, applying additional study and review is something the Department may consider in the future, contingent on the availability of resources. HUD also notes that consideration of environmental justice is a requirement for grantees under § 58.5(j), consistent with HUD's policy goals, including pursuant to E.O. 14096, as well as the consideration for environmental justice requirements under NEPA. HUD notes that responsible entities are required to complete an acceptable 8-step decision making process, that public input must be captured throughout that process, and that such process avoids placing the burden of compliance on community members.

HUD agrees that providing language from the Voting Rights Act or a 60-day public comment period could further public awareness. However, HUD believes that using requirements similar to Section 203 of the Voting Rights Act and quadrupling the required public comment period would cause significant economic harm to projects ready to complete environmental reviews and move towards construction. Additionally, while HUD would encourage grantees to utilize the tools of Federal partners in the completion of their environmental justice reviews, HUD has no plans to mandate the use of any particular tool for environmental justice analysis with this regulation as no one tool is suitable for every type of project HUD funds.

Under § 55.4 of the final rule, HUD-acquired properties sold after foreclosure would include the same notification requirements as those sold in other manners even where no rental subsidies were applied. HUD contends that the final rule will cut down on the properties sold where little information on flood hazard status was available so that homebuyers could make better informed decisions.

HUD notes that public participation in planning and implementation projects subject to review under NEPA is strongly encouraged. HUD believes that communities need to play a substantive role in the development of these plans and implementation of these actions because helps to ensure those communities are taking positive steps to be a part of their own solutions. That said, while HUD appreciates accounts of community members' lived experiences, flood modeling and mapping based on the standards described in this rule, like the FFRMS Federal agency tool in development by the White House Flood Resilience Interagency Working Group and the FFRMS Science Subgroup, with input from CEQ, OSTP, FEMA, NOAA, and HUD, is expected to be available at a consistent and nation-wide scale.

HUD appreciates the commenters' feedback regarding flood insurance resources for homeowners and notes that while this rule does not require flood insurance to be obtained beyond the FEMA-mapped 1-percent-annual-chance floodplain, it does encourage it. As has always been the case, grantees may extend additional requirements for flood insurance beyond the HUD minimum. Additionally, many HUD programs, like CDBG–DR, do allow for flood insurance to be subsidized for a period where it is a required mitigation post construction completion.

HUD appreciates the commenters' feedback that online posting improves accessibility for public noticing. HUD suggests that project sponsors work with their regional HUD representatives to help them achieve greater levels of accessibility and remove any other barriers their potentially affected project populations may face in their attempts at participation in the 8-step decision making process.

c. Program Standards

Several commenters pointed to disparate standards and requirements that they assert will exacerbate disproportionate adverse impacts on affordable housing residents and communities of color.

One commenter urged HUD to adopt the same higher floodplain management standards Department-wide, stating that not expanding higher standards across HUD programs may exacerbate inequalities.

Another commenter offered a direct and specific critique of the higher floodplain management standards FHA-insured market rate multifamily housing is subject to under the MAP Guide as compared to public housing. This commenter also urged HUD to increase resilience for manufactured housing residents (*e.g.,* facilitating public investments in adaptation projects, mandating stricter building codes, increasing access to disaster recovery funds, and incentivizing siting manufactured housing on safer areas).

HUD Response: HUD contends that this rule will have a beneficial impact on communities at greatest risk for flooding and that making those communities resilient in the face of climate change will help them continue to thrive in the future. Furthermore, HUD believes that the requirements in this rule will not have a disproportionate adverse impact on affordable housing residents and communities of color.

HUD appreciates the commenters' concerns regarding higher floodplain standards Department-wide beyond those programs covered by the Minimum Property Standards. The vast majority of other HUD programs are subject to floodplain management standards laid out in the revisions to part 55. While some HUD programs have historically implemented higher floodplain management standards, all HUD programs subject to part 55 will now be required to implement the same more protective FFRMS standard. Following implementation of the final part 55 and part 200 rules, HUD programs may issue program-specific guidance to implement these more protective requirements.

While HUD agrees with the commenter that FHA insured multifamily programs are currently subject to the standard from the MAP Guide and thus, a higher standard than public housing programs which are subject to part 55, HUD notes that the part 55 revisions align floodplain management standards across these programs—both FHA insured multifamily and public housing programs will be subject to the FFRMS floodplain management requirements.

HUD appreciates the commenter's feedback regarding increasing resilience for manufactured housing residents. It should be noted that under part 55, HUD has historically considered MHUs as site-built housing and therefore subject to the same part 55 requirements under various HUD programs. Part 55 does not apply to FHA's Single Family insured mortgage programs. In this final rule, HUD has made a small revision to clarify the Department's historical position that using HUD assistance for the new siting of MHUs has the same environmental requirements as building and substantially improving site-built housing under 24 CFR part 55.

d. Concerns About Disparate Impacts on Housing Supply

Several commenters raised concerns that restricting affordable housing development and rehabilitation in floodplains, along with a lack of elevation data available to establish the FFRMS, will disproportionately harm low-income and rural communities who are less likely to be able to afford relocation outside floodplains, unless HUD provides additional funding and waivers and increases the per-unit maximum limits. One commenter urged HUD to provide waivers for those most impacted by the rule's curtail of development. Another commenter stated that HUD should consider a practical alternative for developing in floodplains in these areas to avoid excluding rural communities in need of affordable housing.

HUD Response: HUD believes that to align with the goals of E.O. 13690 and E.O. 11988, Federal investment should not place vulnerable populations in risky flood-prone environments and promoting development in the floodplain will place harm on low-income populations. Federal investment in the construction of multifamily and/or public housing in riskier areas prone to flooding does not increase the availability of safe affordable housing units. It is HUD's goal to disincentivize continued Federal investment in high-risk flood-prone areas. HUD encourages grantees to seek practicable alternatives to development in floodplains through the 8-step decision making process.

3. Suggestions How HUD Can Further Incorporate Equity Considerations Into This Proposed Rule

Several commenters recommended that HUD prohibit use of fill dirt to achieve elevation requirements to avoid the damaging consequences of stormwater runoff on adjacent properties and communities, which are often lower-lying and most vulnerable. One commenter stated that where fill is necessary, HUD should require projects to retain the volume of water on site equivalent to the volume of fill used.

Several commenters asked HUD to provide additional and inclusive opportunities for communities historically disproportionately affected by flooding to provide feedback to the Department, during and beyond the public comment period.

One commenter asked that outreach include: clear communication of implementation timelines; broad and extensive training for public officials and stakeholders; and stakeholder partnerships across mitigation, housing, land use, floodplain management, and education sectors focused on engineering, architecture, and environmental science curricula nationwide. This commenter explained that education and clear implementation timelines are essential to prevent potential negative real-estate market impacts, especially in communities that already experience disproportionate adverse impacts of flooding. Another commenter asked HUD to provide additional detail and public engagement on how HUD will consider environmental justice impacts of Department actions.

Several commenters urged HUD to provide additional financial and robust technical assistance targeted to communities of color and low-income communities to help offset costs and break down barriers to implementing the rule. One commenter encouraged

HUD to provide (or require housing authorities to provide) renters insurance, property recovery assistance, and temporary housing, prioritizing Black, Hispanic, Indigenous, and low-income communities that experience disproportionate impacts of climate change and inequitable access to the resources to rebuild after disasters. This commenter reasoned that because renter's insurance is often more expensive in low-income communities and communities of color and HUD programs do not require insurance, these communities often experience property loss that resonates for generations, whereas higher-income people are more likely to be made whole. Further, this commenter explained that critical disaster recovery resources are often denied to, or delayed in reaching, marginalized communities.

Another commenter urged HUD to commit substantial funding and staff to the following actions to ensure equity goals are met: communicating flood risks, potential loss, and environmental justice implications across its portfolio and monitoring and enforcing implementation and compliance.

One commenter described the requirement to coordinate the 8-step decision making process with public engagement associated with environmental justice as a good first step in working towards considering environmental justice impacts, which must be paired with greater affordable housing development outside of the floodplain. This commenter encouraged HUD to proactively provide buyout funding with relocation assistance for repetitive loss properties.

HUD Response: HUD does not mandate how a structure may be elevated and leaves that authority to local jurisdictions who have a better understanding of the necessary engineering needed for foundations in their area. This is also true with regard to the needs of the community when it comes to water runoff from properties.

HUD will continue to work with our local partners and stakeholders to ensure the best possible technical assistance and support can be provided which helps our partners achieve efficient, compliant, and effective floodplain management. HUD intends to provide specific technical assistance to responsible entities to ensure a smooth transition to any new requirements. HUD agrees that clearly communicated requirements and implementation timelines are a necessary part of any successful regulatory update.

HUD notes that the rule does maintain but does not expand previously instituted flood insurance requirements for HUD projects within the 1-percent-annual-chance floodplain. HUD strongly encourages flood insurance for projects located in the FFRMS floodplain to minimize financial losses, but it is not mandated. HUD or the responsible entity may also require flood insurance beyond the minimums established by the FDPA when necessary to minimize financial risk. Renter's insurance does not generally cover floods and is not considered a requirement under the rule.

HUD appreciates the commenters' sentiment that additional funding should be made available to HUD to ensure flood risks are adequately addressed throughout its portfolio. Should funds be congressionally appropriated for flood resilience, HUD would enthusiastically utilize them.

Definitions

A. General Comments on Definitions

Some commenters requested that HUD ''put all definitions at the top of 24 CFR part 55.''

HUD Response: HUD intends to maintain the format and structure of part 55. As such, the definitions section will be maintained in its current location at § 55.2 and not relocated to § 55.1.

B. ''Critical Action'' Definition at Proposed 24 CFR 55.2(b)(3)

One commenter found the definition of ''critical action'' in § 55.2 to be vague. The commenter said this vagueness would make it challenging to align with the standards set forth in this proposed rule and recommended revising the definition, both to make it clearer as to what facilities would be included and to expand its reach.

Several commenters supported the inclusion of ''community stormwater management infrastructure'' and water treatment plants under the ''critical action'' definition. Other commenters requested that HUD define ''community stormwater management infrastructure.'' Commenters said that if the definition includes any stormwater development associated with multifamily construction, including offsite, the definition could be applied to any site at or below the 0.2-percent-annual-chance floodplain elevation, based on the definitions for FFRMS included in the proposed language.

HUD Response: HUD's definition for ''critical action'' comes from E.O. 11988 and guidance issued by the Federal Interagency Floodplain Management Task Force and is considered the same definition for these actions by Federal agencies and departments. As such, HUD has determined that the definition is sufficient to provide guidance and flexibility as needed for practitioners to implement the rule as it stands and disagrees that a definitive list is necessary or advisable.

HUD disagrees that the definition of ''community stormwater management'' could be applied to any stormwater development associated with multifamily construction. As discussed in the proposed rule, the revised definition of critical actions specifically references water treatment plants as examples of a utility or service that would be considered as critical actions. This makes evident that the change is intended to focus on larger infrastructure level projects and not smaller upgrades to most individual structures.

C. ''FFRMS Floodplain'' Definition at Proposed 24 CFR 55.2(b)(4)

One commenter suggested including a very clear definition of what is meant by the ''horizontal floodplain'' for each approach where it applies. The commenter went on to suggest that New York State's guidance document for the Community Risk and Resiliency Act could provide model language.

Another commenter expressed concern that HUD is proposing to use a different definition of ''floodplain'' than is used by FEMA to establish FIRMs. The commenter urged HUD to consider applying terminology and standards consistent with FEMA's. Another commenter asked HUD to clarify if the definition of floodplain applies to a FEMA-recognized 1-percent-annual-chance floodplain or the HUD-recognized FFRMS floodplain. This commenter said that assuming the latter, this represents additional administrative burden and can result in reduced property values compared to similarly located multifamily properties.

HUD Response: HUD appreciates the commenters' suggestion to use the New York State guidance on Community Risk and Resiliency Act as a model for the horizontal floodplain definition. Additionally, HUD understands that some people may have a hard time visualizing what the horizontal extent of a floodplain is without maps created by FEMA. As such, HUD intends to create implementation guidance that includes supportive materials and references to existing tools, such as the FFRMS Floodplain Determination Job Aid,[40] to help individuals identify and visualize

[40] *See https://www.fema.gov/sites/default/files/documents/fema_ffrms-floodplain-determination-job-aid.pdf.*

the horizontal extent of the FFRMS floodplain.

Under Executive Orders 13690 and 14030, HUD, like all Federal agencies, is directed to update its floodplain regulations to be consistent with the FFRMS. Though all agencies are required to comply, not all are able to comply at the same pace. HUD continues to work closely with our interagency partners to ensure that our rules are as aligned as possible and that tools developed by NOAA and FEMA are compatible with our regulatory framework. HUD and FEMA continue to work closely together in these efforts to ensure consistency of guidance. In addition, FEMA has already begun implementation of the FFRMS, in part, through policy and guidance, thereby this regulatory revision will better align with FEMA's current approach to FFRMS requirements.

D. ''Impervious Surface Area'' Definition at 24 CFR 55.2(b)(9)

One commenter stated that runoff coefficients vary greatly among surfaces, including lawn and other surfaces not generally associated with ''impervious surface.'' The commenter recommended that when calculating the effects of projects on receiving waters, metrics be utilized to assess the pre- and post-project runoff calculations to determine appropriate mitigative efforts to minimize impacts to receiving waters and downstream communities.

Another commenter noted that it can be difficult to define whether an entire area is an ''impervious surface'' because some parts of the area fit the definition and some do not. The commenter asked how such a situation would affect the management of an area.

HUD Response: HUD appreciates the commenters' feedback regarding runoff coefficients. HUD policy recommends that project sponsors utilize experts to help them implement effective mitigation activities for all projects with potential to impact wetland and floodplain resources. Professional engineers utilizing best available data and current best practices are recommended where appropriate. These experts can also help determine how permeable various materials are and where they can best be used to mitigate a layered landscape. Additionally, HUD requires the 8-step decision making process to outline necessary mitigations to avoid impacts and to examine practicable alternatives to the project. Because the 8-step decision making process also outlines a public engagement requirement, the public can weigh in on a proposed project to comment on the impervious surface area and its impacts.

E. ''Wetlands'' Definition at Proposed 24 CFR 55.2(b)(13)

Many commenters wrote to support expanding the definition of wetlands. One commenter said that with the expanded definition, HUD can more safely and sustainably carry out its mission in a more streamlined manner. Another commenter reasoned that the expanded definition would provide benefits for soil retention by avoiding flooding. This commenter went on to say that there is greater specificity in how soils may determine which areas are wetlands but that the new definition is a good starting point.

Another commenter stated that the definition of ''wetlands'' in the proposed rule is very similar to the definition in the 1987 Army Corps of Engineers manual, which is employed by the Clean Water Act (CWA) Section 404 regulatory program and Natural Resources Conservation Service. However, the commenter says that such definition does not capture all areas performing wetland functions that benefit storm flow augmentation and enhance resiliency.

The commenter argued that the part of the proposed definition that states ''This definition includes those wetland areas separated from their natural supply of water as a result of activities such as the construction of structural flood protection methods or solid fill roadbeds and activities such as mineral extraction and navigation improvements,'' is unnecessary since the wetland definition is based on ''in-situ'' information rather than geographic location or genesis. The commenter said it is also not clear why the rule states that ''This definition includes both wetlands subject to and those not subject to Section 404 of the Clean Water Act as well as constructed wetlands.''

This commenter suggested that the linkage of wetlands defined under this proposed rule and Section 404 of the CWA, or the Food Securities Act, be removed and that a functional analysis methodology be employed for aquatic resources proposed to be impacted by HUD actions. The commenter said this method would better protect communities and natural infrastructure from the effects of climate change and better preserve those resources functioning to the benefit of the watershed. This commenter further explained that while there are resource areas which may ''overlap'' with other Federal, State, and Tribal regulatory programs, it is worth noting that the intent should be the broad protections of floodplains and their function to ameliorate the effects of climate induced flooding and not merely to replicate Federal program standards.

Several commenters expressed support for a uniform definition of ''wetlands'' across Federal agencies to avoid inconsistent and unpredictable wetland delineations and ultimately unequal application of mitigation measures. Several commenters said wetlands would likely be better protected if the definition of wetlands among Federal agencies could be consistent. Several commenters stated that human error based on misunderstanding of what a wetland is likely results in compliance issues related to unauthorized filling of wetlands.

One commenter argued that HUD should follow the U.S. Army Corps of Engineers and EPA definition of ''wetlands.''

Other commenters wrote that HUD should use the consistent definition of a wetland as defined by the NWI.

Several commenters recommended a clarifying change to the definition of ''wetlands.'' The commenters stated that the definition does not differentiate between ephemeral, intermittent, or perennial streams. They asked HUD to please include the definition of deep-water aquatic habitat in the final rule as it would be helpful to avoid confusion as to whether these mentioned aquatic resources qualify as wetland.

HUD Response: While HUD appreciates the commenters' feedback regarding a broader definition of wetland, it should be noted that the rule does not change HUD's definition of a wetland, it merely clarifies its existing policies that describe wetlands as being more than what is identified on an NWI map. HUD generally agrees that soil profiles can be helpful in determining if a wetland may be present on a site; however, HUD, like many Federal agencies, bases its definition of a wetland on the definition found in Executive Order 11990. As such, many agencies have similar definitions. HUD believes that its definition is sufficient to capture the sensitive areas which are protected under its rules.

While HUD agrees that a functional analysis model could be useful in limited circumstances, the benefits are outweighed by the general complexity of the approach. HUD does not want the rule to be burdensome to its grantees in a way that could limit funding towards necessary programs.

HUD disagrees that all Federal agencies should utilize the same definition for wetlands and that HUD's

definition should be dependent solely on the NWI. Not all Federal agencies fund projects with the same level of potential impact and HUD projects are rarely subject to the permitting requirements of the Clean Water Act. HUD feels that its definition of wetlands is therefore more appropriate for the types of impacts associated with HUD projects.

HUD amended its definition of wetlands to remove reference to things that do not constitute wetlands. This change was made both because it is not necessary to list things that the definition does not cover and avoid confusion about certain areas around deep water aquatic habitats that may be considered wetlands.

HUD intends to release subregulatory implementation guidance to ensure responsible entities utilize compliant processes in their environmental reviews.

F. Recommended Additional Definitions

1. Incidental Floodplain

Several commenters requested that HUD provide a clear definition of the incidental floodplain for public comment. One commenter said this proposed rule would maintain a narrower version of the existing incidental floodplain exception as applied to the FFRMS floodplain (not including floodways, coastal high hazard areas, or within the LiMWA) in proposed § 55.12(g). This commenter said this section would allow projects to proceed without completing the 8-step decision making process where an incidental portion of the project site includes the FFRMS floodplain.

HUD Response: HUD has provided subregulatory guidance and resources on the HUD exchange website to illustrate requirements for approval of a project site, an incidental portion of which is situated in a floodplain. HUD agrees that the rule would maintain a narrower version of the existing incidental floodplain (not including floodways, coastal high hazard areas, or within the LiMWA) and allow those projects that fit under the more limited exception to proceed without completing the 8-step decision making process as stated in Section G of the proposed rule. HUD has also removed § 55.12(g)(3) to avoid duplication and to better align with both existing processes and with the new incidental floodway provisions at § 55.8.

2. De Minimis Improvements

Several commenters requested that HUD define ''de minimis improvements'' in detail.

HUD Response: HUD notes that de minimis improvements, as the name implies, are improvements too trivial or minor to merit consideration. De minimis improvements referenced in § 55.8(a)(1)(ii)(B) include activities that have minimal ground disturbance or placement of impervious surface area to ensure accessibility where permitted by local ordinances and where it does not increase flood risk to the property. HUD intends to provide guidance and technical assistance to help project sponsors ensure any improvements in a floodway are de minimis and utilize the best available engineering practices.

Compliance—New § 55.6 Providing a Process To Complying With This Part, and New §§ 55.8 and 55.10 on Limitations on HUD Assistance in Floodplains and Wetlands

A. New § 55.6, Complying With Floodplain Management and Protections of Wetlands Regulations

One commenter described the new § 55.6 as a useful process for practitioners. This commenter asked HUD to strengthen compliance in the following ways: (1) emphasize floodplain avoidance; (2) require reporting on quality of functional floodplain and wetlands impacted by a floodplain action; and (3) develop methods for tracking cumulative loss of functional floodplains and wetlands.

Several commenters asked HUD to provide the ''Roadmap to complying with this part'' for public comment once available.

Several commenters urged HUD to ensure State, local, Tribal, and regional entities have the tools they need to comply with this proposed rule.

HUD Response: HUD appreciates commenters' feedback on the new § 55.6 on complying with floodplain management and protection of wetlands regulations. HUD agrees that compliance can be strengthened via floodplain avoidance, reporting on impacts to floodplains and wetlands, and tracking cumulative losses. HUD believes that the 8-step decision making process at § 55.20 implements many of these recommendations and HUD will continue to emphasize these best practices via existing and forthcoming subregulatory guidance. HUD notes that the ''roadmap to complying with this part'' is the new § 55.6 language itself that was published for public comment. HUD will continue to support local government and Tribal entities and commits to providing additional guidance and resources to aid in regulatory compliance.

B. New §§ 55.8 and 55.10, Limits to HUD Assistance in Floodplains and Wetlands

Several commenters expressed support for proposed § 55.8(c) requiring that HUD or the responsible identity address severe repetitive loss (SRL) properties.

One commenter urged HUD to pay close attention to rehabilitation of multifamily units where residents have needed evacuation and rescue by emergency personnel (in addition to those who have lost property and/or experienced displacement). This commenter recommended that HUD prioritize protections that break the cycle of loss faced by residents, particularly in communities where SRL properties comprise a significant portion of affordable housing stock. This commenter also noted that FEMA determined that repetitive loss is ''the single most important factor that affects stability of the National Flood Insurance Fund.''

Another commenter stated the threshold for a property being designated as SRL is relatively low and therefore suggested that under proposed requirements at § 55.8(c), HUD or the responsible entity should be required to provide this information to the third party conducting the 5- or 8-step review.

Another commenter encouraged HUD to proactively designate funding for buyers with relocation assistance for SRL properties that will otherwise be subject to increasingly frequent and intense damage due to climate change.

Another commenter stated that properties experiencing repetitive loss should be rebuilt to modern standards that mitigate flood risk.

HUD Response: HUD agrees with commenters that § 55.8(c) is an important provision to protect lives and property and maintain stability of the National Flood Insurance Fund. The intent of this provision is to better protect those living in communities where a significant portion of the affordable housing stock is comprised of SRL properties, particularly those who may have previously experienced displacement. HUD agrees that SRL mitigation requirements should be included in the 5- or 8-step decision making process and notes that §§ 55.8(c) and 55.20(e) of the final rule require disclosure and implementation of FEMA identified SRL mitigation in Step 5 of the process. The mitigation measures identified in Step 5 may be identified by HUD, the responsible entity, or a third-party environmental review preparer.

HUD does not have congressionally appropriated funds specifically for SRL properties, but relocation or other mitigation activities at SRL properties may be eligible under multiple HUD grant programs that fund relocation and other mitigation assistance.

C. HUD Compliance Monitoring

Several commenters asked how HUD will monitor, enforce, and address violations of the proposed rule.

One commenter posed the following specific questions about HUD's current and proposed monitoring practices: (1) What types, and to what extent, do offices outside of HUD's Office of Environment and Energy perform monitoring to ensure assisted properties and proposed sites do not occupy floodways in violation of part 55? (2) How does HUD monitor housing authorities outside of Community Planning and Development (CPD) entitlement communities for environmental compliance? (3) Outside those performed by HUD's Office of Environment and Energy, how does HUD monitor flood insurance for programs administered by FHA Multifamily, the Office of Disaster Recovery, and the Office of Public and Indian Housing? (4) What steps did HUD take following the 2015 HUD Inspector General report, ''Buildings at Three Public Housing Authorities Did Not Have Flood Insurance Before Hurricane Sandy'' to ensure compliance with mandatory flood insurance maintenance under the Flood Disaster Protection Act of 1973? (5) How will HUD exercise its oversight responsibility over properties approved under the proposed § 55.21 to ensure residents are not subject to flooding or repeated floods, or to monitor changes in the mapped floodways, especially increased flood risk over time? (6) Does HUD have staff with the qualifications to review hydrological, hydraulic, and hydrostatic threats to structures from floodways?

Another commenter explained that strong code enforcement—including adequate staffing numbers/expertise and continuing education on code updates and best practices—is necessary to realize public safety and resilience goals, citing evidence that strong code enforcement can contribute to loss reduction by 15–25 percent.

Another commenter urged HUD to commit the following to ensuring compliance with the FFRMS and protections: funds, additional staff, and a comprehensive implementation plan that strategizes data collation on flood risk communications and environmental justice.

HUD Response: HUD will address enforcement and compliance with the rule via environmental monitoring identified at § 58.77(d). HUD's Office of Environment and Energy conducts in-depth environmental monitoring and exercises quality control (via training and technical assistance) for the environmental review activities, including part 55 requirements, performed by responsible entities. Program offices, including FHA Multifamily, Office of Disaster Recovery, and Public and Indian Housing are also responsible for limited environmental monitoring to review compliance. This includes monitoring for compliance with Federal flood insurance requirements for projects involving mortgage insurance, refinance, acquisition, repairs, rehabilitation, or new construction.

HUD has floodplain and wetlands subject matter experts who will review and make recommendations for exemptions requested under the § 55.21 provision. HUD may rely on project engineers, Federal science agencies (*e.g.,* FEMA, U.S. Army Corps of Engineers), and other experts as needed, depending on the nature of the flood risk and the project proposed. To provide further clarity, HUD has outlined the specific minimum requirements to utilize the alternative process from § 55.21 which includes removing all residential units from the floodway, elevating or floodproofing all buildings in the FFRMS floodplain where practicable, and receiving a No Rise Certification for any new improvements in the floodway.

HUD agrees that code enforcement is an important piece of meeting public safety and resilience goals and works with its local partners to ensure HUD programs are compliant with local requirements. HUD also agrees that increased capacity to implement FFRMS via funding, staffing capacity, and data collection is critical and will continue to emphasize this need through proper appropriation and hiring channels. HUD is addressing the 2015 HUD OIG report referenced by the commenter outside of this rulemaking.

Notification of Floodplain Hazard Requirements Under 24 CFR 55.4

A. Support for Notification Requirement

Several commenters expressed support for the proposed changes to notification of floodplain hazard requirements as a critical requirement to ensure buyers, developers, renters, and other stakeholders are fully informed of a site's flood risk and potential direct and indirect costs. One commenter explained that increased transparency of flood risk and benefits of flood insurance creates stronger consumer protection. Another commenter described the notification requirements as morally right.

One commenter stated that the notice of floodplain hazard requirements remedies deficiencies and inconsistencies in State protections, explaining that 21 States have no requirements to disclose to prospective homebuyers past incidents of flooding, flood risk, or flood insurance information, and only 8 States require prospective tenants receive any of these disclosures.

Another commenter explained that these requirements are particularly necessary for publicly subsidized housing, which prospective renters and buyers may assume is safe by virtue of being built by a public agency or housing authority and in accordance with Federal requirements, despite most affordable housing being located in vulnerable areas.

Another commenter stated that HUD's inclusion of detailed notice contents requirements and lease acknowledgements will support consistent implementation of this protection.

Another commenter expressed support for the new proposed § 55.6, which outlines the required process that HUD or another responsible entity must follow in carrying out notification requirements. This commenter urged HUD to commit necessary resources to effectively fulfill notification of floodplain risk obligations across its portfolio.

Another commenter encouraged HUD to require notification as early in the process as possible and in a method and language appropriate to potentially impacted communities.

HUD Response: HUD appreciates the commenters' support for the proposed changes to the notification requirements which ensure buyers, developers, renters, and other stakeholders can make informed decisions about a property's flood risk. HUD agrees that increased transparency creates stronger consumer protection for residents of publicly subsidized housing. HUD notes that the final rule adds the term ''HUD-acquired'' to the list of property types in § 55.4(b) to clarify that properties that had previously been insured by HUD and were then acquired by HUD through default are also subject to the requirements for notification to renters when a property is in a floodplain.

B. Recommendations To Strengthen Notification Requirements

Several commenters asked HUD to strengthen the rule to require that notifications are written in accessible, plain language that is tailored to impacted communities. One commenter asked HUD to amend §§ 55.4, 50.23, 58.43 or 58.59 by adding language access requirements mirroring Section 203 of the Voting Rights Act to ensure that immigrant and other non-English speaking communities have access to hazard notifications and can participate in community engagement. Another commenter stated that notice should be given in as many forms/methods as necessary to reach the community, which may include methods beyond government websites or newspapers of general circulation. Several other commenters encouraged HUD to specifically encourage publication in resources that are free to the public.

One commenter recommended that notification include flood disaster mitigation plans. Another commenter recommended adding emergency preparedness information to the required notification contents on emergency procedures under proposed § 55.4(b).

Several commenters encouraged HUD to work with FEMA to provide useful information to buyers and renters about the value of flood insurance and resources to help people understand how flood insurance policies work.

Another commenter urged HUD to revise the list of exceptions in § 55.12 to include notification of floodplain hazard requirements for property transactions involving repossession, receivership, foreclosure, etc.; as well as HCVs and rental subsidies not associated with a project. This commenter reasoned that HUD-associated foreclosed homes are often resold with scant information.

Another commenter asked HUD to revise the rule to apply the notification requirements beyond floodplain boundaries. This commenter explained that this suggestion is based on this commenter's experience during a tropical storm and projected expansion of flood risk due to climate change.

Another commenter suggested expanding the effort to make sure prospective buyers and renters have adequate information about flood risk and insurance, beyond those living in the floodplain.

HUD Response: HUD intends to provide grantees, applicants, and responsible entities with technical assistance and guidance which will help ensure that notifications are effective and compliant. HUD encourages any property owner to work with their tenants and ensure notices are communicated effectively.

HUD guidance and trainings instruct grantees to translate environmental review public notice documents for relevant limited English proficiency (LEP) populations to meet Title VI requirements for LEP.

HUD notes that while it encourages property owners to share all pertinent information surrounding flood risk for their properties, many communities do not have formal mitigation plans in place. That said, the rule does require evacuation information to be included along with ingress and egress routes.

HUD does not intend to expand the list of exceptions at § 55.12 currently and notes that certain property dispositions are subject to analysis under part 55. While HUD encourages notification of flood risk, HUD does not intend to require that notification for properties outside of the floodplain. HUD encourages grantees to work with Federal partners and disseminate relevant information regarding flood insurance to those in the floodplain.

HUD appreciates the commenters' feedback regarding the expanded notification requirements for renters within the floodplain. HUD believes the notice requirements will help without overly increasing the administrative burden on landlords.

C. Opposition to Notification Requirement

Several commenters objected to expanded floodplain hazard notification requirements, stating that the resulting administrative burden on property owners and management agents could result in reduced occupancy at covered properties compared to similarly located housing.

One commenter added that since regional HUD offices can also require flood insurance, including for properties not within the 1-percent-annual-chance floodplain per HUD's MAP Guide, the fact that flood insurance is available or required does not necessarily indicate a property is within a floodplain. Another commenter urged HUD to strike ''and flood insurance is available for their personal property'' from renter notification requirements at § 55.4(b) and ''the availability of flood insurance on the contents of their dwelling unit or business'' from conveyance restrictions for disposition of real property in § 55.4(c)(2)(i)(B), reasoning that housing providers are not positioned to make definitive statements about flood insurance availability to renters.

HUD Response: HUD strongly disagrees with the commenters' statements that notification of flood hazards to residents is a significant administrative burden on property owners and management agents. A single disclosure necessary to provide tenants the opportunity to make informed decisions about their flood risk is not a significant administrative burden especially in context of other information property owners/management are expected to gather when leasing.

HUD disagrees also that property owners are not positioned to make statements about flood insurance availability for structures that they own. HUD encourages responsible entities and project partners to implement flood insurance requirements beyond the minimums established by the Flood Disaster Protection Act where they feel it is appropriate to minimize financial risk, but going beyond the minimum standard is not required.

D. Requests for Clarification of Hazard Notice Requirement Regulations

One commenter asked if ''floodplain'' covered by hazard notification requirements under the new § 55.4 means FEMA-recognized 1-percent-annual-chance floodplains or HUD-recognized FFRMS floodplains. This commenter stated that if the notification of floodplain hazard applies to FFRMS floodplains, the additional administrative burden caused by this expanded application can result in reduced property values compared to similarly located multifamily properties.

Several commenters asked HUD to provide a standard tenant notification form that meets the hazard notification requirements.

Additionally, several commenters asked HUD to revise the rule to clarify aspects of the notification requirements, which they stated was necessary to carry out the requirements. Several commenters asked HUD to more clearly define the conveyance restrictions moved from current 24 CFR 55.22 to the new 24 CFR 55.4. Several commenters asked for clearer details on the process, including: (1) the method for providing the notification to prospective homebuyers/renters; (2) whether the notification is signed; and (3) who prepares the notification.

One commenter stated that additional guidance or specificity to required notification content is needed to provide any of the information listed (*e.g.,* proximity to flood-related infrastructure, ingress and egress, flood insurance claims disclosure). Several commenters specifically asked HUD to

define what proximity must be included and what information is required regarding ''proximity of a site to the flood-related infrastructure.'' One commenter explained that property owners may not know reliable sources for this information.

One commenter asked HUD what type of notice residents would receive that a floodway is proximate to the site, the risk it poses, and how to relocate during a flooding event.

HUD Response: In the language of the new § 55.4, HUD states that the notification requirements extend to the FFRMS floodplain. HUD contends that if a property were reduced in value due to flood risk, that risk would exist outside of any notification requirement HUD imposes.

HUD intends to release additional guidance and technical assistance to assist grantees to better understand and utilize the conveyance restrictions outlined in § 55.4. HUD intends to provide technical assistance and guidance for compliance with the hazard notification requirements which may include some form templates that grantees can use and what information regarding proximity to the floodplain should be included. Use of these forms will not be mandated in keeping with other public notice documents HUD provides for part 55. HUD contends that any administrative effort necessary to inform renters of their flood risk is not only minimal but necessary for the health and safety of residents. Given the existing requirements necessary in a rental agreement, HUD believes the additional costs of this notification to be de minimis.

HUD intends to provide guidance and technical assistance to grantees, applicants, and responsible entities to help ensure consistent and compliant notice is provided to tenants when their buildings are in the floodplain of concern.

Consolidation and Clarification of Flood Insurance Requirements Under New 24 CFR 55.5

A. Support for Flood Insurance Requirements

Several commenters expressed their support for the new flood insurance provisions in the proposed rule. One commenter suggested the changes will increase transparency and communication of flood risk and the benefits of flood insurance.

Another commenter supported HUD requiring flood insurance beyond the minimum requirements established in the FDPA and said it was prudent and necessarily minimized financial risk. This commenter said that the existing FDPA is insufficient due to inadequate policy limits in an era of rapidly rising home valuations, the fact that the need for flood insurance in flood-prone areas that may be located just ''outside'' of a designated Special Flood Hazard Area (''SFHA''), and the fact that FEMA has only mapped 1/3 of the Nation's floodplains.

Another commenter said that the flood insurance provisions in the proposed rule are an important step to ensuring the sustainability of America's housing stock. Incorporating concepts such as CISA, additional freeboard protection, open space foundation systems and the limitation of the use of fill within SFHAs are higher standards proven to reduce risk.

Another commenter agreed that HUD must ''prudently'' manage its FHA-insured mortgages by first understanding the portfolio's actual exposure to flood risk and the extent to which FHA homeowners must purchase flood insurance policies. The commenter said flood risk management policies at all levels of government are critical to reducing national flood losses.

Another commenter said that all consumers should be encouraged to obtain flood insurance, especially given the increasing flood risk due to climate change.

One commenter suggested that HUD expand the requirement for flood insurance for all assisted properties that have previously flooded, especially CDBG–DR projects.

HUD Response: HUD appreciates the commenters' feedback regarding their support for the flood insurance provision and the increase in transparency and communication for flood risk. While the Department also appreciates the sentiment behind wanting to expand the flood insurance requirements outside of the special flood hazard area, HUD intends to strongly encourage flood insurance outside of those areas rather than mandate it. HUD does not have the authority to change or alter the NFIP regulations as those regulations are implemented by FEMA.

HUD appreciates the commenters' sentiment regarding the need to improve flood risk management policies at all levels of government. The Federal government can help set a national regulatory floor for things like elevation and insurance standards, but local and State governments are encouraged to evaluate their own regions and develop code requirements that suit their needs if they go beyond the minimum set at the Federal level. This rule, which applies to the CDBG–DR program, explicitly encourages flood insurance for all properties within the FFRMS floodplain and beyond the 1-percent-annual-chance floodplain mapped by FEMA. Additionally, the rule clarifies that HUD, or the responsible entity, may require flood insurance coverage beyond the minimums to minimize financial risk.

B. Flexibilities and Exemptions to Requirements Sought

One commenter urged HUD to allow flexibility for Public Housing Authorities to use different methods of transferring or retaining risk in proposed § 55.5(b). This commenter said that requiring flood insurance up to replacement value for such entities may impact the market for flood insurance nationwide.

Another commenter asked that any floodplain requirements be limited only to ''Federally funded projects.'' This commenter said that since HUD does not originate loans or fund projects through the FHA Multifamily Program, but rather, it insures those loans through the FHA, projects insured by these programs should not be required to meet the mandates of the FFRMS.

HUD Response: HUD appreciates commenter concerns regarding the market for flood insurance nationwide. HUD has a responsibility to ensure that publicly funded investments in public housing authorities in higher risk areas like floodplains are protected against loss through insurance. Through Executive Order 11988, HUD is directed to protect Federal investments including those providing insurance of mortgages. Additionally, insurance markets are not generally limited by supply and more policy holders tend to drive down actuarial risk-based rates. HUD and FEMA both offer homeowners several resources to help them differentiate between types and obtain appropriate levels of flood insurance for their structures.

For FHA multifamily mortgage insurance, the project is submitted to HUD as an application for approval prior to construction or rehabilitation. Therefore, the project is subject to NEPA and part 55. In contrast, newly constructed single family homes have already been constructed when an application for mortgage insurance is submitted to HUD. Therefore, newly constructed FHA insured single family properties are only subject to the Minimum Property Standards—NEPA and part 55 do not apply.

C. Opposition to Flood Insurance Requirements

Several commenters opposed the proposed rule's changes to flood insurance requirements and language in the proposed rule stating that HUD ''strongly encourages'' flood insurance for all structures within the FFRMS floodplain. These commenters argued that maintaining flood insurance for all structures within the FFRMS floodplain will make it prohibitively expensive to build and operate necessary housing, and the costs will be passed along to residents in the form of higher rents and higher housing costs. Several of these commenters went on to say that though purchasing flood insurance beyond what is required may mitigate future financial losses, it may require some consumers to suffer current financial losses in the form of higher operating expenses. One commenter emphasized that they agree that flood insurance is an essential tool to manage potential future costs but that it can also make homes in risky areas less affordable.

HUD Response: HUD believes that flood insurance is an important component of flood resilience. While HUD does not require flood insurance when a structure is located outside the 1-percent-annual-chance floodplain, the Department supports and strongly encourages owners to obtain it as HUD knows that structures within the FFRMS floodplain are still at greater risk of flooding than those outside the floodplain. The Department recognized and acknowledged in the RIA that the rule has the potential to increase construction costs for housing. After weighing the increased cost against the potential savings associated with the benefit of more resilient housing stock, HUD determined it to be cost effective to move forward with the rule, including flood insurance requirements. HUD notes that the flood insurance requirements referenced in this rule are mandated by statute under the Flood Disaster Protection Act of 1973 (42 U.S.C. 4012a(a)); the regulatory language in § 55.5(a) applicable to financial assistance within the special flood hazard area restates the flood insurance requirements that are already required by statute outside of this rule. HUD does recognize though that while flood insurance can be a financial burden it is only required within the 1-percent-annual-chance floodplain. The rule does not require flood insurance for all structures within the FFRMS floodplain but instead strongly recommends it.

D. FEMA Floodplain

Several commenters urged HUD not to expand its requirements beyond FEMA mapping, asking HUD to limit flood insurance requirements to only structures located in the SFHA per FEMA maps. These commenters said that utilizing CISA maps would create a disjointed approach to flood insurance.

Another commenter urged HUD to work with and support FEMA in its recommendations to reform the NFIP.

One commenter suggested HUD rephrase the statement ''. . . the NFIP plays an important role in minimization measures to reduce flood losses,'' reasoning that flood insurance does not minimize losses but enables the insured to recoup some of the material losses.

HUD Response: HUD appreciates the feedback from commenters concerned with flood insurance outside of the SFHA and FEMA-mapped 1-percent-annual-chance floodplain. As stated in response to opposition to requirements, the rule does not extend flood insurance requirements to the FFRMS floodplain outside of the FEMA mapped 1-percent-annual-chance floodplain. The rule only strongly recommends flood insurance in those areas. This is in keeping with FEMA's requirements under NFIP regulations. HUD will continue to work with its Federal partners and support their efforts to increase the Nation's resilience to disaster through various programs, including NFIP.

HUD appreciates the comment but believes that the recoupment of flood damages may be considered a reduction of flood losses.

E. Limitations for Multifamily Housing

One commenter supported increasing coverage limits but asked that HUD recognize the limitations on coverage in more expensive areas, particularly for multifamily buildings. This commenter explained that while some large residential buildings may be able to purchase private excess coverage, options in most areas are limited and often cost-prohibitive for affordable housing providers. This commenter also said that NFIP coverage limits are insufficient to cover the costs of flood damage in multifamily homes, as well as in mixed-use buildings, and urged HUD to support efforts to increase coverage for such buildings. This commenter added that private insurers can refuse coverage to at-risk buildings.

Another commenter emphasized that the insurance industry is increasingly refusing coverage in high-risk areas.

Other commenters said there are unique challenges for flood insurance for multifamily housing. Commenters said stories of multifamily buildings are usually elevated ten or more feet and if the first floor of a multifamily building is already elevated 2–4 feet above the Base Flood Elevation per the FEMA flood elevation, providing increased flood coverage for units located some 22–24 feet+ above the Base Flood Elevation would create unnecessary financial burdens to developers of multifamily projects in cases where no practical alternative to locating a project in the floodplain may be identified.

HUD Response: While HUD appreciates the commenters' feedback regarding insurance coverage limits, HUD does not have the authority to change or alter the NFIP regulations as those regulations are implemented by FEMA. Generally, HUD supports the insurance of multifamily buildings in flood risk areas to the maximum extent possible, noting that they do often face significant challenges protecting the full value of the structure under NFIP. Where there is no practicable alternative to locating a HUD-assisted activity in proximity to flood sources, HUD will continue to require elevation or floodproofing where allowable to ensure these buildings and their tenants are protected.

F. Requests for Clarity on Flood Insurance Requirements

One commenter expressed confusion over the language ''strongly encourages'' and asked HUD to consider replacing this language and to make clear what its expectations would be for flood insurance for those properties outside the FFRMS floodplain.

Several commenters sought clarity on how HUD would determine if flood coverage equivalent to the full replacement cost of the structure would be required. These commenters recommended that the final rule make it clear for developers to know exactly what will be required for flood insurance when making decisions to acquire or develop land for housing use and not to leave it up to the individual developer's discretion.

Other commenters wondered how HUD would enforce the acquisition and maintenance of flood insurance if it is not required by regulation. Who at HUD will have that authority and what training will they receive in order to make them qualified to make this determination?

HUD Response: As discussed in response to opposition to flood insurance requirements above, flood insurance is only required within the 1-percent-annual-chance floodplain. To be clear, encouragement to obtain flood insurance outside the 1-percent-annual-

chance floodplain is not a requirement although grantees are allowed to expand requirements beyond the HUD minimums. HUD does not believe the binary status of obtaining or not obtaining flood insurance requires any particular specialized expertise to determine. Acquisition and maintenance of required flood insurance will be reviewed on a project-specific basis as part of program monitoring requirements, as applicable.

HUD will continue to utilize the direction of the MAP guide to determine the flood insurance coverage requirements for Multifamily FHA projects and the Section 232 Handbook for Healthcare FHA projects.

Exceptions

A. Incidental Floodplain Exceptions

1. Support for Limited Exceptions

Several commenters expressed support for the exceptions at § 55.8(a)(2) for floodplain restoration activities, explaining that the proposed language is more flexible than the current standards, while incurring de minimis impacts to the floodway.

One commenter expressed their support for proposed language to clarify and ensure that floodways assistance would only be allowed for limited floodplain restoration activities and only after engaging in the 8-step decision making process and justifying that there are no practicable alternatives. This commenter explained, citing FEMA guidance, that floodways naturally convey floodwaters downstream and thus designing a floodway and regulating development within that floodway is necessary because any obstruction increases likelihood and elevation of flooding both upstream and downstream.

Several commenters supported allowing safe installation of utility lines to cross floodways where it is the most practicable method for connecting existing lines, reasoning that this is practical because utility mains are often in low-elevation areas and likely to be safe because development codes often require tie ins in these areas and utility line instillation causes only temporary impacts.

One commenter supported allowing removal of man-made structures from the floodway/floodplain. This commenter recommended that HUD amend the rule to make clear that projects restoring wetlands, floodplains, rivers, or other aquatic habitats in alignment with FFRMS objectives are exempt from the 8-step decision making process.

One commenter supported equivalent protections in the LiMWA as the V Zones. Another commenter endorsed the improved protections in Coastal A zones or areas within the LiMWA.

HUD Response: HUD appreciates the support from commenters regarding the exceptions at § 55.8(a)(2). That said, based on feedback received, HUD has made language changes in this section to more clearly delineate the purpose of the section in relation to §§ 55.12(g) and 55.21. Specifically, in § 55.12(g), HUD has removed the requirement for a permanent covenant such that the exemption more logically follows the review process for projects with an incidental floodplain. In § 55.21, HUD has clarified that to be eligible for the alternate processing for existing projects, the project must meet certain minimum eligibility criteria. These minimum criteria include the following: removing all residential units from the floodway, elevating or floodproofing all buildings in the FFRMS floodplain, including existing structures where practicable, and receiving a No Rise Certification for any new improvements in the floodway. HUD intends to produce additional guidance and technical assistance material which will outline the types of activities allowed on properties containing a floodway but not within the floodway itself. HUD notes that under CPD–17–013, it has outlined a methodology that allows certain linear infrastructure to cross a floodway where it is appropriately mitigated and there are no practicable alternatives. HUD also notes that under § 55.12(c), the restoration of wetlands and floodplains is exempt from the 8-step decision making process.

HUD appreciates the support for the equivalent protections across the V zones and the LiMWA. HUD's intent with this revision is to increase the resilience of coastal construction.

2. Exceptions Are Not Protective Enough

Several commenters expressed concerns that proposed exceptions provide insufficient floodway protection. Several commenters urged HUD to prohibit all development and reconstruction within floodways, the deepest and highest velocity portion of drainage, to avoid certain continued losses to HUD projects and safety risks to residents.

One commenter urged HUD to prohibit both critical and noncritical building actions in floodways and coastal high hazard areas, instead of allowing noncritical actions under the circumstances listed in the proposed rule. This commenter reasoned that the focus must not only be on ceasing development in floodways, but also on restoring and re-establishing natural infrastructure. This commenter supports the proposed rule permitting noncritical actions within the remaining two categories—wetlands/1-percent-annual-chance floodplain outside floodways and non-wetlands area outside of the 1-percent-annual-chance and within the 0.2-percent-annual-chance floodplain—but only on a case-by-case basis and requiring the 8-step decision making process.

This commenter supported the proposed amendment prohibiting placing ''community stormwater management infrastructure and water treatment plants'' in floodways due to high risk of becoming inoperative in a flooding event. However, this commenter urged HUD to go further by amending § 55.1(c)(2) to read: ''any critical action located in a coastal high hazard area *or within the existing 100-year or 500-year floodplain maps, to be amended*.'' This commenter also asked HUD to add ''schools'' to the definition of ''critical action'' reasoning that damage to schools causes significant disruption to students and communities.

Several commenters asserted that new construction in floodplains, even under the 8-step decision making process, will have the following negative impacts: (1) waste scarce financial resources on resilience and mitigation activities; (2) subject households, predominantly low-income families, to damage and danger; and (3) continue legacies of exclusionary zoning practices.

One commenter urged HUD to remove floodplain exceptions for residential structural infrastructure (utility lines, pipelines) from the proposed rule. This commenter explained that flooding results in catastrophic impacts to nearby residential drinking water when water, sewer, and wastewater utilities are in flood-prone areas, citing joint EPA and FEMA guidance that these utilities face unique risks in flood-prone areas and that it is cost intensive to build them to resilient standards.

Several commenters asked HUD to provide a clear definition of the incidental floodplain for public comment. One commenter asked HUD to clarify whether part 55 requirements would be triggered if an undeveloped portion of a property is within the floodplain, while the structure itself is not.

One commenter posed the following questions: (1) How did HUD determine that paving floodway areas for basketball and tennis courts is de minimis? (2) Is there a critical number

of projects that cannot avoid paving floodway areas such that this exception is necessary?

Several commenters requested explicit guidance on the methods of utility installation that are permitted/prohibited.

Several commenters stated that HUD should defer to NFIP/local regulations for floodway actions.

HUD Response: HUD appreciates the feedback from commenters regarding concerns over exceptions HUD uses to allow work on properties with a floodway on site. HUD disagrees that all work needs to be prohibited from floodways, noting that many functionally dependent uses must be built in these areas in order to work properly. HUD does not exempt this work from the 8-step decision making process; however, work in these sensitive areas is often the most critical to review for impacts, alternatives, mitigations, and engagement with the public. Under the rule, HUD will prohibit any new residential construction in the floodway with the goal of ensuring the potential to harm human life is minimized. Because of feedback received, HUD has revised the language of § 55.21 to make it clear that residential units must be removed from the floodway, all buildings in the FFRMS floodplain must be elevated or floodproofed where practicable, and a No Rise Certification must be obtained for any new improvements in the floodway, in order for the exception to apply. HUD intends for the alternative processing for existing nonconforming sites outlined in § 55.21 to be used in very rare circumstances and only under the strict review and sole discretion of HUD's Office of Environment and Energy and the Assistant Secretary for Community Planning and Development, where HUD determines the proposed action is protective of human health and the environment. Depending on the nature of the proposed activities in or near a floodway, the alternative processing may require substantial mitigation measures and appropriate documentation to obtain, if approved.

HUD disagrees that funding spent on any mitigation determined necessary through an 8-step decision making process would be considered a ''waste of resources.'' Mitigation that reduces risk and protects life and property can only be seen as a benefit for populations that would otherwise be at increased risk of flooding. Additionally, HUD contends that supporting the resilience of structures in the floodplain better protects those structures against future loss and disagrees that increasing community resilience continues the legacy of exclusionary zoning.

HUD notes the commenters' feedback regarding wastewater treatment and stormwater facilities; however, these facilities, while critical actions, are also functionally dependent on being near water. HUD did not intend to disallow functionally dependent facilities from receiving funding with this rule and as such has allowed an exception for functionally dependent projects which meet the mitigation requirements at § 55.8(a)(2) and complete an 8-step decision making process in accordance with 24 CFR 55.20. This change brings HUD in line with its Federal partners like FEMA in allowing the funding of certain types of functionally dependent facilities.

HUD disagrees that all schools need to be included as critical actions because schools do not have permanent residents and will not be occupied during an emergency.

Examples of de minimis improvements listed in § 55.8(a)(1)(ii)(B) include activities that have minimal ground disturbance or placement of impervious surface area to ensure accessibility where permitted by local ordinances and where it does not increase flood risk to the property. HUD intends to provide grantees, applicants, and responsible entities with technical assistance and guidance to ensure any improvements in a floodway are de minimis and that only compliant work is allowable under this part.

Any action allowed by HUD would also need to be compliant with NFIP and local regulations.

HUD intends to release technical assistance and guidance to help grantees, applicants, and responsible entities better determine when it is appropriate to utilize the incidental floodplain exception at § 55.12(g). HUD notes that projects with an undeveloped portion of the property located within the floodplain will be exempted from part 55 analysis if all requirements under § 55.12(g) are met.

B. Inapplicability of 24 CFR Part 55 to Certain Categories of Proposed Actions Under § 55.12

1. Expanded Exception for Floodplain and Wetland Restoration and Preservation Activities

Several commenters expressed support for the expanded flexibility for parks and recreation uses in combination with restoration and preservation activities. Several commenters explained that the proposed exception will increase the quality of life for HUD-assisted tenants by providing opportunities to connect with nature and the floodplain and wetland habitat where they live, without significant disruption to those areas' function.

One commenter urged HUD to amend the rule to add incentives or favor parks and greenspace projects that incorporate green infrastructure to restore/protect natural ecosystems like wetlands, prairie, riparian corridors, and bayous. This commenter explained that preserving remaining riparian and wetland infrastructure is proven to slow flood waters avoiding future flooding damages, while also providing communities with necessary parks and green space for communities. This commenter cited a study showing that affluent bayou communities received greater government investment in flood protection following Hurricane Harvey than low-income communities as reasoning for going beyond the proposed mandated process towards an incentive model.

Another commenter asked if HUD could expand the flexibility for restoration activities compatible with beneficial floodplain and wetland function beyond parks and recreation activities.

Several commenters asked HUD to explain what kinds of ''structures and improvements designed to be compatible with the beneficial floodplain or wetland function'' would be allowed and asked for this clarification to be included for public comment.

HUD Response: HUD appreciates the support from commenters regarding the expanded flexibility for parks and recreational space within the floodplain. It is HUD's hope that these spaces are maintained as a benefit to HUD-assisted tenants as an improvement to their quality of life without adversely impacting the floodplain.

HUD believes that by allowing greenspace restoration within the floodway, HUD can better incentivize restoration and protection of riparian buffer spaces and wetlands which provide compounding resilience benefits across the floodplain.

HUD does not currently have plans to expand the flexibility for restoration activities beyond what the rule allows because there is no funding for HUD to provide additional incentives. HUD intends to provide additional guidance and technical assistance to help grantees, applicants, and responsible entities discern which improvements and structures are allowed and compatible with beneficial floodplain or wetland function.

2. Removal of LOMA/LOMR Exceptions

Several commenters expressed support for removing both part 55 exceptions for sites that have received LOMAs/LOMRs. Several commenters specifically supported the removal of the conditional LOMA/LOMR exception, explaining that provisions to disincentivize the use of fill will protect natural and beneficial floodplain and wetland functions. Several commenters further reasoned that adding fill to floodplains causes increased flood risk to surrounding properties/areas and expansion of the floodplain. One commenter stated that disincentivizing the use of fill will protect neighboring residents, property, and the environment. Another commenter expressed support for limiting fill within special flood hazard areas. Conversely, several other commenters opposed removing the LOMA/LOMR exceptions. Several argued that doing so would result in an unnecessary administrative burden on borrowers and lenders; and that additional government agencies—HUD and the USACE—would add unnecessary bureaucratic processes. Several commenters asked HUD to define which governmental agency would have final authority to determine if a floodplain change is required. One commenter added that the additional layer of bureaucracy created by requiring projects that are outside the 1-percent-annual-chance floodplain under FEMA's requirements to complete the 8-step decision making process will create confusion and regulatory conflicts and delay much needed housing. This commenter urged HUD to defer to FEMA's expertise on whether a property is outside of a floodplain.

Several commenters asked HUD to clarify whether the requirement to elevate sites with no known or previously occurring flood risk to the respective required standards under each approach will result in requiring completion of the 8-step decision making process before adding fill, per § 55.12(c)(8). These commenters added that if this would trigger the 8-step decision making process, it would cause administrative burden on borrowers and lenders.

Several commenters specifically urged HUD to retain the conditional LOMA/LOMR exception. Several commenters stated that the current conditional LOMR/LOMA system is more effective for determining when fill may be added to remove sites from the 1 percent annual chance floodplain because FEMA, civil engineers, and local authorities understand the impact to adjoining sites and provide sufficient governmental oversight. These commenters stated that HUD's reasoning for removing the exception on conditional LOMAs/LOMRs to avoid incentivizing adding fill is contradictory or is a moot point, considering that other portions of the proposed rule require the use of fill without limits due to the impact on adjoining areas.

Several commenters disagreed that excepting conditional LOMA/LOMR projects from the 8-step decision making process incentivizes filing floodplain areas, stating that the exception allows developers to incorporate plans to minimize floodplain impacts in the early stages of planning, prior to civil plans required as part of the 8-step decision making process.

HUD Response: HUD appreciates the commenters' support for the removal of exemptions based on LOMAs/LOMRs. As LOMAs/LOMRs act to remove an area or structure from the base floodplain and not the FFRMS floodplain, HUD did not think they would provide the necessary information to remain as an exemption to part 55. Additionally, HUD did not want to incentivize the use of fill in the FFRMS floodplain.

HUD disagrees with commenters' feedback that removing the LOMA/LOMR exemption creates an unnecessary administrative burden on borrowers and lenders because LOMAs/LOMRs do not remove sites from the FFRMS floodplain. Regardless of whether or not exempting conditional LOMA/LOMR projects from the 8-step decision making process incentivizes the use of fill, misaligned Federal processes and policies inherently create a greater burden on practitioners attempting to comply with conflicting rules, so the exemption must be removed to reduce these burdens. As the FFRMS floodplain is defined by the processes laid out in the rule, HUD or the responsible entity has final authority to determine if a site is located in the FFRMS floodplain, based on the appropriate FFRMS definition for the locality. HUD agrees that the rule will expand HUD's regulatory footprint beyond the FEMA-mapped 1-percent-annual-chance floodplain. However, under E.O. 13690 HUD is directed to review a broader area and account for an increasing flood risk over time through the use of the FFRMS floodplain. While LOMAs/LOMRs can be effective tools at determining when sites have been removed from the FEMA mapped 1-percent-annual-chance floodplain, they have no bearing on the state of a site with regards to the FFRMS floodplain.

Additionally, HUD notes that other Federal agencies like FEMA are working on updating their own floodplain management regulations to account for E.O. 13690 and increasing flood risks to Federal investments.

HUD notes that § 55.12(c)(8) is being removed but if a project were to add fill to a site located in the FFRMS floodplain, it would likely trigger the 8-step decision making process under the rule. That said, the rule does not require that elevation be completed with fill and in fact, discourages its use for compliance.

HUD disagrees with commenters' feedback that removing the existing LOMA/LOMR exemption will affect the ability of developers to incorporate mitigation in the early stages of planning. Because the NEPA process mandates that environmental review be complete prior to any choice limiting actions being taken, any mitigations for a project site must be considered prior to construction regardless of the status of a FEMA FIRM change.

C. Exceptions in Proposed §§ 55.13 and 55.14

Several commenters expressed support for the proposed exception for special renewable energy projects, stating that the exception is forward-thinking and will likely result in increased use of energy-efficient technology in HUD projects.

One commenter urged HUD to revise the rule to provide the following limits on this exception: (1) do not permit a streamlined 8-step decision making process for energy efficiency projects that replace systems or appliances with fossil fuel-fired system or appliance under 24 CFR 50.13 and 50.14; and (2) add language to 24 CFR 55.13(f) requiring that proposals to install fossil fuel infrastructure to improve energy efficiency have no feasible electric alternative.

One commenter asked HUD to clarify the threshold for ''limited potential to adversely affect floodplains or wetlands'' for energy efficiency projects seeking the § 55.13(f) exception.

HUD Response: HUD appreciates the commenters' feedback regarding exceptions for renewable energy projects. HUD disagrees that it is necessary to limit this exception to apply only to energy efficiency projects that do not use fossil fuels. HUD wishes for this exception to benefit any project that improves energy or water efficiency or installs renewable energy that does not meet the threshold for substantial improvement and does not wish to limit fossil fuel projects to only those where there is no electric alternative.

HUD intends to provide guidance and technical assistance to grantees,

applicants, and responsible entities acting as HUD to ensure they can properly assess projects seeking the exemption at § 55.13(f) and understand which projects have the potential to affect floodplains and wetlands.

D. Revisions to Categorical Exclusion From Further Environmental Review Under NEPA Under § 50.20(a)(2)(i)

1. Support for Proposed Revisions to Categorical Exclusion

One commenter expressed support for proposed revisions that allow timelier remediation of existing floodplain properties if HUD ensures that any impact resulting from an increased footprint would be fully addressed in the 8-step decision making process. This commenter provided maps of existing affordable housing units overlaid with FEMA flood maps showing many single family homes in flood zones that have already lost money and explained that allowing remediation for these homeowners will allow more low-income homeowners to decide for themselves whether to rehabilitate their homes. This commenter further explained that they would not support this amendment but for the ''hard look'' required by the 8-step decision making process that this commenter hopes will discourage floodplain development.

Another commenter stated that if the 8-step decision making process is part of a full environmental review, the information sought is addressed under NEPA and HUD should avoid repetition.

HUD Response: HUD appreciates the commenters' feedback regarding HUD's plans to align its part 50 regulations with its part 58 regulations.

HUD notes that compliance with part 55, including completion of the 8-step decision making process when required, is included as part of HUD's NEPA compliance regulations under parts 50 and 58.

2. Opposition to Proposed Revisions to Categorical Exclusion

One commenter opposed removing the qualification to categorical exclusion where a rehabilitation project would increase the footprint of a structure within a floodplain or wetland under § 50.20(a)(2)(i). This commenter reasoned that foregoing full NEPA analysis of projects receiving HUD funds that would adversely impact critical habitat and flood mitigation services is counterproductive. This commenter also asked HUD to expand wetland identification protocols beyond the National Wetlands Inventory where necessary.

This commenter also suggested the following revisions to the categorical exclusion list at § 50.19: (1) require environmental review when HUD supports new construction projects with fossil fuel utility service or homebuying assistance for homes that are not all-electric, and (2) qualify equipment purchase and operating costs under § 50.19(b)(13) and (14) to exclude costs associated with newly installed fossil fuel-fired systems and appliances. This commenter explained that fossil fuel extraction and combustion contribute to climate change, increasing the likelihood and severity of flooding and that further government subsidy of climate change inducing housing is an irresponsible use of taxpayer funds. Further, this commenter suggested that HUD could reallocate savings to increase sustainable affordable housing.

HUD Response: HUD disagrees with the commenter's feedback that aligning its part 50 categorical exclusion with its part 58 exclusion will allow adverse impacts to critical habitat and flood mitigation. HUD has utilized this approach for part 58 reviews since 2013 and has not seen the described adverse impacts. Projects that meet this categorical exclusion remain subject to the requirements under part 55 as well as other laws and authorities at 24 CFR 58.5 and 50.4. The potential adverse impacts of a project do not change based on the determination of which entity is responsible under NEPA. Furthermore, HUD notes that before applying a categorical exclusion to a proposed action, HUD or the responsible entity assesses the proposed action for extraordinary circumstances that would require preparation of an environmental assessment or environmental impact statement. Additionally, HUD addresses potential climate change impacts for projects that require an Environmental Assessment or environmental impact statement through the climate change environmental assessment factor. Additional edits to the categorical exclusions at parts 50 and 58 are outside the scope of this rulemaking.

E. U.S. Army Corps of Engineers Permit Exception

Several commenters opposed the proposed removal of § 55.28 when a permit has been obtained from the USACE for a proposed HUD-assisted construction activity in a jurisdictional wetland outside of the floodplain. These commenters questioned whether the USACE consistently implements the 8-step decision making process per FEMA guidance in implementing E.O. 11988 and urged HUD to revise the rule to require that prior to granting relief, HUD confirm that other agencies have adequately completed the 8-step decision making process.

HUD Response: HUD appreciates the commenters' feedback regarding the removal of § 55.28. However, HUD contends that this section was unnecessary because this exemption was rarely utilized by grantees and, under the new § 55.26, HUD maintains a method for adopting another agency's 8-step decision making process when appropriate. Through § 55.26, HUD intends to reduce unnecessary duplication of Federal regulatory processes to support the development of compliant and resilient projects.

Wetlands

A. Approach to Identifying Wetlands in § 55.9

1. Support for Changes to § 55.9

Several commenters supported HUD's changes to § 55.9, broadening its approach for identifying wetlands. Several other commenters acknowledged their support and cited the important biodiversity wetlands provide, along with the ways that wetlands naturally regulate the climate. One commenter supported HUD for looking beyond a ''desktop review'' of landscapes to determine wetlands.

Several commenters specifically supported HUD's proposal to broaden the screening of wetlands beyond the use of USFWS' NWI. One commenter quoted from the USFWS' explanation that the NWI methodology does not effectively identify all types of wetlands and a ''margin of error is inherent.'' Noting this plus the United States Supreme Court's rollback of wetlands protections under the Clean Water Act, the commenter supported backup protocol for identifying wetlands and urged HUD to use the full extent of its legal authority to protect these critical habitats and the important flood mitigation functions they provide.

HUD Response: HUD appreciates the commenters' support for § 55.9 of the proposed rule; however, HUD notes that the rule does not change HUD's definition of a wetland, it clarifies it as being more than what is identified on an NWI map.

2. Recommendations To Increase Wetland Identification Requirements

One commenter stated that the NWI data varies in accuracy and that in order to ensure the accuracy of wetlands determinations, such a determination should be confirmed by an on-site analysis that includes an assessment of the functions of the ecosystem. This commenter went on to say that the analysis should be confirmed with the

USFWS, along with further consultation with the USACE, U.S. Environmental Protection Agency (EPA), and/or State or Tribal aquatic resource regulators. This commenter agreed with HUD's proposal to assess ''biological'' rather than regulatory wetlands and urged HUD to develop a functional analysis methodology in consultation with the Academy of Science and Tribal and State programs for aquatic resources proposed to be impacted by HUD actions.

One commenter stated that resource identification needs to be done in combination with other geospatial tools, such as Light Detection and Ranging (LiDAR) technology. The commenter stated that NWI should not be a primary presence/absence indicator of wetlands, but rather used as part of a suite of remote tools and ''on the ground'' analysis including a functional analysis method to determine the role the resource is playing in flood resiliency and abatement. This commenter recommended additional consultation with the USACE, the EPA, and/or State or Tribal aquatic resource regulators.

Other commenters added that the NWI indicates the general presence of wetlands on a site but fails to accurately capture the full delineation of wetlands at ground-scale, especially for the identification of smaller wetlands of an acre or less. These commenters also supported the proposed requirement for a ''visual assessment'' of a site to help identify wetlands. The commenters suggested that HUD revise the requirement to require evaluation of all undeveloped sites using one of the three proposed methods to ensure that wetlands identification on an undeveloped tract is not left to the visual assessment of an untrained practitioner.

One commenter urged HUD to clearly articulate that a physical review of a property by a qualified wetland scientist is necessary by adding the word ''physically'' to § 55.9(b). If not, this commenter asked HUD to add language explaining in detail how the development community should meet the proposed rule's intent of slowing the destruction of wetlands within communities.

Several commenters emphasized the importance of trained professionals conducting the visual assessment. Other commenters asked whether there are any qualification requirements for the personnel performing the visual screening and whether an environmental review consultant would be acceptable. One commenter asked who at HUD would be adequately trained to perform the visual observation and what this training will consist of.

HUD Response: Existing HUD policy has historically encouraged the use of tools and delineations that go beyond the NWI mapper to determine if wetlands are present on a site. The rule's methodology for wetland identification streamlines that policy into a more actionable and functional process for practitioners and reviewers. It is important to HUD that this rule maintains strong protection for wetlands without increasing regulatory burden. HUD agrees that wetlands are critical habitat and play a vital role in flood mitigation for communities.

HUD disagrees that either an on-site wetlands delineation or LiDAR assessment is necessary or appropriate for every wetland review. NWI maps and visual observations of a site provide sufficient information for responsible entities to preliminarily determine if further investigations are warranted. Requiring fully detailed delineations by certified wetland scientists for all projects on undeveloped land would constitute a significant financial and administrative burden that HUD does not wish to impose on its grantees at this time.

It is HUD's intent to provide subregulatory guidance to help grantees navigate the wetland review process including desktop review, visual inspection, and when delineation performed by a certified wetland scientist would be considered necessary and appropriate. Any of these options may be appropriate and will depend on the associated needs of the project involved. Additionally, HUD may consult with other agencies like USACE, EPA, or USFWS as necessary to ensure potential impacts are appropriately mitigated and/or any necessary permits are obtained. During the 8-step decision making process, HUD also requires responsible entities to engage with the public and interested parties like local, Tribal, and non-profit groups with an interest in the resource.

HUD has floodplain and wetlands subject matter experts who will work with grantees, applicants, and responsible entities to ensure compliant reviews are performed in accordance with E.O. 11990.

3. Concerns With Changes to § 55.9

Some commenters suggested if a wetland is suspected, sites should be evaluated by the NWI, State, and local wetland and stream maps, hydric soil maps, topographic maps, and historical imagery. These commenters said hydric soil maps should be included in the environmental review as part of wetlands protection, similarly to the United States Department of Agriculture (USDA) requirements. The commenters went on to say that if suspected wetlands are identified through these desktop methodologies, the property should be reviewed by a wetlands consultant and receive comment from the USACE.

Another commenter wrote that the several approaches to identifying wetlands in this proposed rule will produce inconsistent and unpredictable results. The commenter said HUD's goal in updating its wetland regulations is ''to streamline them, improve overall clarity, and modernize standards.'' This commenter believes the most effective approach to realizing these goals is through the adoption of the universally recognized definition of wetlands developed by the USACE and EPA.

Several commenters submitted a more specific concern that the meaning and intent of ''visual indication'' is not clear. The commenters urged HUD to clarify the ''visual indication,'' and said such vague terminology may lead to widespread inconsistency in the application of the wetland identification process.

These commenters also asked whether the use of just one of the evaluations (USFWS consultation or NRCS Soil Survey with further evaluation performed by the environmental review preparer) would be sufficient to rule out the presence of wetlands, without the need to complete a wetland delineation.

Several commenters recommended that HUD completely remove the first method from its final rule. The commenters argued that the job of the USFWS is not to consult on wetlands, rather sites should be evaluated by the NWI, State, and local wetland and stream maps, hydric soil maps, topographic maps, and historical imagery and the property should be reviewed by a wetlands consultant with comment from the USACE.

One commenter pointed out that it is not clear in the proposed rule whether the three methods provided are in order of preference or if any one of them can be selected to rule out the presence of wetlands. Commenters also requested that HUD clarify whether once a site has screened inconclusive for potential wetlands, a developer may rely on citing just one of the three methods outlined to conclude there are no wetlands onsite.

HUD Response: HUD agrees with commenters that when NWI maps are unavailable or responsible entities feel they may be inaccurate, HUD does allow grantees to use best available information to support their

conclusions. This can include local and State maps, soil maps, topographic maps, and historical imagery. This has historically been, and continues to be, HUD's approach to wetlands review under the rule. HUD disagrees that the rule's approach to wetland identification will create inconsistent and unpredictable results. The definition for wetlands as used by the USACE and the EPA stems from the Clean Water Act and covers a narrower definition of wetland which is tied into their respective permit authorities.

It is HUD's intent to provide subregulatory guidance which will help grantees navigate the wetland review process including visual inspection and when delineation would be considered necessary and appropriate.

As the Federal agency tasked with managing the NWI mapper, USFWS is the first agency consulted if a potential issue or deficiency with the NWI is identified.

B. Limitations of HUD Assistance in Wetlands in § 55.10

Several commenters argued that the rule should prohibit all new construction in wetlands. One commenter said that subjecting construction in wetlands to the 8-step decision making process is not enough and that the importance of wetlands in lessening the impact of both riverine and coastal flooding should spur HUD to take additional steps to prevent new construction within them. The commenter emphasized that wetlands and wetland vegetation provide low-maintenance storm mitigation by storing water and slowing the speed of flood waters, along with serving as storm surge protectors. This commenter also noted that coastal wetlands are often viewed as cultural resources by the surrounding communities who view the continued encroachment of development into these areas as a destruction of their heritage. One commenter urged HUD to use stronger language prioritizing the preservation of wetlands and firmly assert that wetland and riparian corridors should be avoided. The commenter opined that Federal dollars should not be used to develop properties that put people in harm's way.

Several commenters emphasized the importance of nature-based solutions and existing green infrastructure known to slow flood waters and protect communities such as wetlands, prairies, riparian corridors and/or bayous as well as reconfiguration of the project footprint and incorporating resilient building standards. One commenter asked HUD to add specific provisions to the proposed rule protecting wetlands and incorporating green infrastructure and to conduct an economic analysis through case studies on various high-flood-prone communities to show that protecting the riparian corridors and wetland green infrastructure would be more cost beneficial than allowing development and covering properties with insurance.

One commenter recommended that all Federal agencies calculate the effects of wetland loss through funding and permitting programs in accordance with E.O.s 11988 and 13690. The commenter noted that Step 5 in FEMA's ''Guidelines for Implementing E.O. 11988 and E.O. 13690,'' published October 8, 2015, states that the concepts of ''Minimize, Restore, Preserve . . . apply if a proposed action will result in harm to or within the floodplain'' and defines ''harm'' to apply to both lives and property, and natural and beneficial floodplain functions. Therefore, the commenter went on to say, it would seem logical that any unavoidable impacts to natural infrastructure within a floodplain, including wetlands, should be mitigated for within the sub-watershed effected and provide ecosystem services to the same locality where the impacts occurred.

Another commenter asked if the impact to one or more acres of non-jurisdictional wetlands is proposed, how HUD will manage the mitigation requirement. This commenter urged HUD to define the one-acre mitigation policy. The commenter noted that compensatory mitigation for jurisdictional wetlands is well-established and widely understood but the prescription of compensatory mitigation for disturbance to more than one acre of non-jurisdictional wetlands is not clear in the proposed rule, and HUD should indicate that it is not required for non-jurisdictional wetlands.

Another commenter asked for clearer information about the costs and process of purchasing compensatory mitigation for non-jurisdictional wetlands.

Another commenter stated that they do not agree that wetlands mitigation should be limited to impacts greater than one acre since any loss of wetlands and floodplains impacts communities and water quality by impairing the ability of watersheds to provide resiliency and flood storage capacity during storm events. This commenter also said that they do not agree with an approach whereby mitigation would be translocated to an in-lieu-fee or banking instrument which is not providing direct benefits to the impacted reach of the waterway and associated floodplain.

HUD Response: HUD disagrees that new construction should be entirely barred from wetlands and that the 8-step decision making process is not enough. While HUD agrees that wetlands are important and play important roles as critical habitat and flood protection, an outright ban on construction would have significant adverse impacts on development nationwide. HUD will continue to fund new construction in wetlands where it has been demonstrated that no practicable alternative exists and that all necessary mitigation measures have been taken. HUD acknowledges that many communities identify coastal wetlands as cultural resources or important heritage sites and notes that consultation requirements on historic and culturally significant resources are covered under the National Historic Preservation Act (NHPA). No part of this rule exempts sites from review under the NHPA or any other applicable Federal laws and authorities.

HUD agrees with commenters on the importance of nature-based solutions. HUD is seeking to strengthen the commitment to use nature-based floodplain management approaches where practicable by identifying specific strategies and practices that have proven effective in increasing flood resilience and environmental quality, identified in § 55.20(e). These strategies include encouraging the use of natural systems, ecosystem processes, and nature-based approaches when developing alternatives for consideration where possible.

HUD continues to work with FEMA and other Federal partners to minimize any adverse impacts to wetlands from HUD funded projects. In addition, in cases where multiple funding sources are anticipated, HUD recommends utilizing the Unified Federal Review (UFR) to assist in the collaborative cross-agency/Department discussions to resolve any differences across the agencies and ensure cohesion in funding and goals for the project. Additionally, it should be noted that HUD has procedures in place to adopt the environmental reviews of other Federal agencies to avoid unnecessary duplication of effort.

HUD intends to provide grantees, applicants, and responsible entities training and technical assistance to assist them in utilizing appropriate mitigation measures when non-jurisdictional wetlands have unavoidable impacts. Historically, these mitigations have included various forms of compensatory mitigation, and the rule is not intended to change this provision. The use of any compensatory

mitigation is not viewed as a substitute for the requirement to minimize impacts to the maximum extent possible.

Changes to the 8-Step Decision Making Process

A. Roles and Responsibilities

One commenter asked HUD to clarify who will conduct encroachment and other floodway analysis and how that analysis is to be done under the new § 55.21. This commenter stated that FEMA's current guidance is for the community or developer to conduct it and explained that most local permit officials are not qualified and thus require the developer to pay for an engineer to conduct encroachment analysis.

HUD Response: HUD has floodplain and wetlands subject matter experts who will review and make recommendations for exemptions requested under the § 55.21 provision. HUD and responsible entities may rely on project engineers, Federal science agencies (*e.g.,* FEMA, USACE), and other experts as needed, depending on the nature of the flood risk and the project proposed.

B. Consistency With FFRMS and New Sections

One commenter expressed support for the proposed updates to the 8-step decision making process to provide clarity and alignment with the FFRMS.

One commenter recommended that wherever HUD defines FFRMS floodplain identification methods, it should consistently use terms referring to both elements of the definition—flood elevation and floodplain extent.

Several commenters asked for clarification whether improvements within the 0.2-percent-annual-chance floodplain will trigger the 5- or 8-step decision making process considering that CISA maps are not currently available and HUD does not predict national coverage for years. These commenters urged HUD to make FFRMS guidance clear and methodical to avoid leaving room for interpretation.

Several commenters suggested that HUD define ''areas required for ingress and egress,'' a triggering ''action'' under § 55.20(a), and that the definition should exclude public thoroughfares, which these commenters reasoned including could stretch the covered area further from a development than necessary. One commenter cautioned that including ingress/egress to an action may increase HUD or property owner liability for harm to residents occurring on roads off the subject property. This commenter stated that neither HUD nor borrowers are authorized or responsible for road conditions of the subject property, citing that a majority of flood-related fatalities occur on roads during floods.

Several commenters urged HUD to address how the FFRMS applies to infrastructure projects by incorporating mitigation considerations (*e.g.,* useful life, ingress/egress) and requirements for infrastructure projects in § 55.20(e). These commenters asked HUD to mandate elevation for ingress and egress to flood-prone areas, as well as mitigation measures based on the site's entire landscape for critical utilities where elevation is not possible (*e.g.,* stormwater). These commenters reasoned that the proposed steps in § 55.2(b)(3) are insufficient because grantees increasingly use CDBG, CDBG–DR, and CDBG–MIT funds to construct and improve bridges, water utility lines, and other critical infrastructure not subject to the structure-specific elevation requirements in § 55.20, despite the preamble's recognition of the vulnerability of essential infrastructure to flood damage.

HUD Response: HUD appreciates the commenters' support for the proposed changes to the 8-step decision making process to provide clarity and alignment with FFRMS. HUD recognizes that floodplain terminology can be confusing for grantees, applicants, and responsible entities and HUD intends to provide significant technical assistance and training to help ensure that practitioners are using the correct language to refer to various aspects of the floodplain.

As described in the proposed rule, where CISA is unavailable to define the FFRMS floodplain, grantees, applicants, and responsible entities will use the 0.2-percent-annual-chance floodplain if it is available for non-critical actions and FVA +2 feet when it is not. Note that it is the FFRMS floodplain that will trigger the need for a 5- or 8-step decision making process, regardless of the method used to define it. For critical actions, projects must utilize the higher of FVA +3 feet or the 0.2-percent-annual-chance floodplain if it is available. HUD expects to provide training and technical assistance covering the various methods for defining the FFRMS floodplain along with the 8-step decision making processes to grantees, applicants, and responsible entities which should help them maintain compliance across their project portfolios. HUD disagrees that the 8-step decision making process is insufficient for infrastructure projects and notes that elevating infrastructure is often not practicable. In these cases, HUD requires infrastructure be floodproofed and protected through other means than strictly elevating it. CPD–17–013 outlines that critical infrastructure like bridges needs to be elevated or floodproofed to the 0.2-percent-annual-chance floodplain. This is also in keeping with the FEMA requirements for critical facilities.

HUD notes that the 8-step decision making process for critical actions does require projects to consider ingress and egress along with alternative locations for the project with the intent of removing it from the floodplain if practicable. Access to sites is vital to the functional use and safe evacuation of a site during a flood and therefore must be considered as part of the 8-step decision making process. HUD disagrees that consideration of ingress and egress will create any greater liability for property owners than otherwise would exist if they maintained unsafe conditions. Road conditions during a flood are not considered in this analysis beyond their ability to function as ingress and egress to a site.

C. Public Notice and Comment in Steps 2 and 7

Several commenters urged HUD to shift the onus from residents having to look to newspapers or government websites to identify projects that may affect them. One commenter urged HUD to require providing comprehensive proposal details to impacted communities and soliciting their feedback in as many forms/methods necessary, beyond posting to a government website or newspaper. Several commenters urged HUD to shift notice and comment requirements to a community-led planning model, mandating earlier engagement of impacted communities, carried through project lifecycles. These commenters asserted that more substantive participation of impacted communities will: increase likelihood that residents will support projects and help to address any obstacles; improve community understanding of flood risks and how they can individually prepare; reinforce a sense of community; and lead to better project outcomes.

One commenter specifically sought revisions to § 55.20 to require that flood risk assessment and project design criteria steps be co-produced with impacted residents and require flood mitigation assessment to weigh community members' lived experiences (*e.g.,* intended uses, flood susceptibility, population-specific concerns) equally with technical modeling assessments. This commenter explained that residents' familiarity with the property allows them to identify characteristics/

risks that site developers and engineers may otherwise miss, such as stormwater issues and critical ingress/egress.

Several commenters sought clarification on the deadline meant by ''earliest possible time of a proposal'' for sending required Initial Notice required under § 55.20(b). In clarifying ''earliest possible time,'' these commenters asked HUD to consider a developer's planning process, explaining that developers would need detailed plans to prepare the initial notice and that developers may not be able to respond to comments until later in a project timeline. Another commenter asked if the proposed rule would change public notice publication timing.

One commenter urged HUD to amend § 55.20(b)(2) from providing ''a minimum of 15 calendar days . . . for comment on the public notice'' to a minimum of sixty (60) calendar days, which this commenter stated will create no additional delay to the lengthy building process or economic harm, while providing necessary opportunity for public awareness.

Several commenters expressed support for the option to publish Steps 2 and 7 notices on an appropriate government website as an alternative to local news outlets.

Several commenters raised concerns that the public's lack of access to, or knowledge of, government-operated websites may decrease the efficacy of public notices. One commenter asked HUD to consider requiring publication in local newspapers circulated in print and online, characterizing this as a more practical alternative to government websites.

Several commenters sought clarification on what classifies as an ''approved government website'' for public notices and who at HUD would be authorized to ''approve'' websites. Several commenters asked if ''government website'' refers to local, State, or Federal government websites. Commenters also asked HUD to clarify who at HUD has the authority to determine what is or is not an ''approved'' site. Several commenters asked HUD to detail the roles and responsibilities for public notice.

Several commenters asked whether HUD would publish the 8-step analysis and Finding of No Significant Impact (FONSI) on HUD's website for public comment. One commenter asked what the required length of comment periods for a FONSI for choice-limiting actions under part 50 would be and what the typical comment period length for these actions is. Another commenter asked HUD to describe its current notice and comment process for floodway projects under part 50 at both the environmental assessment and ''categorically excluded subject to'' levels of review.

HUD Response: HUD appreciates commenters' feedback regarding the solicitation of public engagement through additional means other than government websites or newspapers; however, HUD will not currently expand the requirement. HUD recognizes that community outreach requires valuable time and resources and while HUD would hope that all affected community members participate in any public comment process, it cannot mandate participation. HUD follows the public engagement considerations as laid out in 24 CFR 50.4, 24 CFR 58.59 and 40 CFR parts 1500–1508 where appropriate. While HUD appreciates anecdotal community input regarding flood risk and encourages projects to consider this information, HUD cannot rely solely only on this information for decision making. Because the 8-step decision making process for floodplains and part 55 compliance falls under laws and authorities at §§ 58.5 and 50.4 for applicable project activities, grantees, applicants, and responsible entities must complete all parts of the process prior to engaging in any choice limiting actions. HUD field staff from the Office of Environment and Energy are available to assist in determining if it is the right time to publish their early notices under § 55.20(b).

HUD disagrees with the commenters' statement that increasing the early notice publication timeframe from 15 to 60 days would cause no additional project delays. HUD believes an increase of this magnitude at this time would cause significant project delays and provide little benefit for public awareness. HUD does not intend to increase the early public notice period at § 55.20 to 60 days at this time.

HUD appreciates the commenters' support for the use of government websites to distribute public notices under part 55. This rule requires that an official government website used for public notification must include accessibility features and languages necessary to ensure the affected community has access to provide meaningful public feedback. The rule clarifies responsibility for public notices falls to the responsible entities who complete the 8-step decision making process. HUD intends to provide grantees with necessary training and guidance to support their efforts at ensuring any government websites used are appropriate. Additionally, under Title VI of the Civil Rights Act of 1964, Executive Order 13166, and in accordance with the U.S. Supreme Court ruling in *Lau* v *Nichols,*[41] recipients of Federal financial assistance are required to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. This means that a government website would need to meet the accessibility requirements all HUD programs are subject to in order to be considered acceptable.[42] The rule does not change the responsible entity's responsibility for publication.

D. Clarifications and Recommendations

One commenter expressed support for the proposed Step 4 impact evaluation language, while stressing that in addition to evaluating the impacts, the evaluation process must include mitigating loss of natural functions within the impacted watershed where avoidance is not feasible.

Several commenters sought clarification in the rule of what information is needed to meet the requirement to demonstrate that runoff from a proposed development would not impact surrounding properties under § 55.20(d)(1)(ii)(C), and whether it would be sufficient to document compliance with local requirements. These commenters explained that many local ordinances require total stormwater volume not increase from pre- to post-construction; however, the addition of fill to any floodplain will generally result in watershed changes, including increased stormwater volume.

One commenter asked HUD to work with Federal partners to develop post-regulatory guidance and training to inform Steps 4 and 5 that clearly define: the values of floodplains, wetlands, and nature-based solutions; the ecosystem process/functions that generate these values; and the bio-geomorphology (ecological interactions between hydrology, geomorphology, and biology of floodplain environments) and attributes of ''functional'' floodplains. This commenter stated that the proposed rule and Guidelines for Implementing Executive Orders 11988 and 13690 fail to adequately describe these values and attributes, resulting in this commenter regularly seeing local agencies incorrectly interpret ''functional'' floodplains and allow projects to proceed that fail to protect and restore floodplain functions (*e.g.,* planting grass for parks). This commenter explained the value of supported floodplain bio-geomorphology, along with the four attributes that must be attained to

[41] 414 U.S. 563 (1974).

[42] 68 FR 70968.

achieve it, that HUD should incorporate into guidance: (1) connectivity between the floodplain and its river/stream; (2) necessary timing, magnitude, duration, and frequency of flow from connected water source; (3) special scale; and (4) habitat and structural diversity.

HUD Response: HUD appreciates the commenters' support for the proposed Step 4 impact evaluation language. HUD recommends that project specific environmental review questions be addressed by Regional and Field Environmental Officers from HUD's Office of Environment and Energy. HUD notes that the rule does not mandate how elevation is achieved and recommends that applicants concerned about runoff on their property utilize methods of elevation that do not increase surface flow.

HUD intends to provide technical assistance and guidance to grantees, applicants, and responsible entities for all 8 steps of the 8-step decision making process to help ensure compliance with E.O. 11988, E.O. 11990, and E.O. 13690.

Due to the potential for an increased regulatory burden, HUD does not intend to require grantees, applicants, and responsible entities to track the locations and quantities of growth and development in the floodplain over time as part of their 8-step analysis.

HUD notes that § 55.20(d)(ii)(C) does not forbid a project from impacting surrounding properties; however, those impacts must be considered and documented. HUD projects are required to follow all relevant laws and authorities.

E. Environmental Justice Requirements

Several commenters expressed support for this provision as a step towards HUD's responsibility to address environmental justice and equity impacts of floodplain management and decision making processes.

One commenter urged HUD to target robust technical assistance towards communities with limited resources to implement the 8-step decision making process.

Another commenter urged HUD to engage the public in developing guidance, and for that guidance to address the following topics: (1) detail how HUD will weigh environmental justice impacts; (2) provide streamlined decision making for activities that mitigate flood risk or wetland loss or that provide co-benefits; and (3) detailed actions manifesting HUD's commitment to nature-based floodplain management approaches.

One commenter raised concerns that the proposed environmental justice review provisions fail to mandate public participation and substantive analysis of proposed actions by including flexible language that incentivizes not engaging historically underrepresented communities in land decisions that impact them. Specifically, this commenter urged HUD to delete ''(if conducted)'' from § 55.20(f)(2)(iii) (''If the proposed activity is located in or affects a community with environmental justice concerns . . . the reevaluation must address public input provided during environmental justice outreach (if conducted) . . . .''). This commenter reasoned that permitting developers to forego environmental justice outreach where census data/mapping programs do not identify a community of concern inappropriately shifts the burden onto community members to identify and mitigate hazards and could result in HUD supporting development near hazardous sites that are not yet documented on a map. This commenter also stated that non-discretionary public outreach requirements align with other HUD rules, citing HUD's environmental justice worksheet's instruction that project planners should always mitigate environmental justice impacts.

The same commenter also urged HUD to revise the proposed rule to clearly define the substantive analysis necessary to adequately conduct an environmental justice review, suggesting that HUD incorporate guidance from other administrative agencies, citing the EPA's Legal Tools to Advance Environmental Justice as an example. This commenter explained that analysis must account for the cumulative risks from all environmental hazards, beyond flooding itself, illustrating with the example that discriminatory zoning, concentration of hazardous uses, and disinvestment in infrastructure mean that when flooding occurs, communities also experience hazard contamination and harmful emissions from producers' increased emergency outputs.

Several commenters stated that if the 8-step decision making process is part of a full environmental review, NEPA will address environmental justice information and discouraged requiring duplication.

HUD Response: HUD appreciates the commenters' support for the proposed rule's steps towards addressing environmental justice and equity impacts of floodplain management and decision making processes. HUD intends to issue updated guidance for advancing environmental justice and coordinating public engagement under the 8-step decision making process with any ongoing engagements associated with environmental justice goals. Additionally, HUD created a new Environmental Assessment factor for environmental justice in 2022 which requires environmental review preparers to outline potential project impacts and mitigations for environmental justice.

HUD disagrees that the requirement for engaging communities facing environmental justice issues inappropriately shifts the burden of identifying and mitigating hazards onto those communities that are not identified as communities of concern. HUD mandates public participation in the 8-step decision making process in Steps 2 and 7 which require an early and final public notice respectively regardless of the community affected. Feedback received as part of the public participation process is intended to inform decision making related to site locations and mitigation measures, but the responsibility for identifying and mitigating hazards is limited to HUD and the responsible entity. HUD also notes that environmental justice is a required consideration as listed at 24 CFR 50.4 and 58.5 and is not limited to part 55. The rule simply requires coordination of public outreach efforts if they exist.

Elevation and Floodproofing

A. Overall Resilience

1. Elevation Is Insufficient To Increase Flood Resilience

Several commenters urged HUD to keep in mind that FFRMS is more than just an elevation standard, but rather a broad framework to increase flood resilience and preserve floodplains.

One commenter urged HUD to focus more on the overall health of the floodplain itself rather than the ability of a structure to withstand a flooding event. This commenter said that focusing on the effects an activity has on floodplains and analyzing and mitigating for the benefit of the watershed effected would comply with the intent of E.O. 11988 and E.O. 13690.

One commenter asked HUD to revise the rule to encourage a wide range of resilience measures, to better conform with E.O. 13690's requirement that agencies use nature-based approaches wherever possible. This commenter reasoned that while the proposed elevation standards have a potential to significantly reduce damage, nature-based measures like wetlands restoration are more effective over a large area, in cost and environmental values, citing a case study comparing cost effectiveness of nature-based and coastal adaptation. Another commenter pointed out that ''resilience'' is not

defined in the proposed rule and that the elevation standards demonstrate a concern only for lost property rather than harm to people after a flood event.

Another commenter noted that for some projects, including those deemed as ''critical'' (such as community assets like hospitals, fire stations, and water treatment facilities) elevation alone might not offer the most cost-effective or durable protections. This commenter urged HUD to require careful consideration for what constitutes ''critical'' and assure protection of ingress, egress, and continued functioning rather than simply protection of the structure itself.

One commenter urged HUD to draw a firm line against allowing ''floodproofing'' in the FFRMS floodplain for any ''new'' build or substantial improvement, or alternatively, clarify that floodproofing through elevation be accomplished through pier and beam construction and not by pouring concrete slabs. The commenter noted that this was especially important given HUD's shift to CISA maps because, without additional funding, those maps could take many years to update and release. The commenter also believed that HUD's attempt to mitigate by adopting the 8-step decision making process is insufficient and would allow continued development within the current 1-percent-annual-chance floodplain maps.

HUD Response: FFRMS is more than an elevation standard, it is a flood risk reduction standard designed as a flexible framework to increase resilience against flooding and help preserve the natural values of floodplains. Resilience in this context is the ability to withstand and recover quickly from flood events. HUD contends that increasing the resilience of the built environment through elevation standards decreases the risk to people who reside in those structures. HUD must account for the impacts of its actions and activities on floodplains and wetlands per E.O. 11990, E.O. 11988, and E.O. 13690. Many HUD programs like CDBG–DR and CDBG–MIT fund wetland restoration and nature-based solutions to flooding issues. HUD agrees with the commenter that nature-based solutions are an effective way to reduce damage and has added language in this final rule at § 55.20(c)(1)(ii) to encourage nature-based solutions as alternatives to avoid floodplain and wetland impacts. HUD also encourages the use of nature-based solutions where feasible as a resilience measure per the guidance found in the Community Resilience Toolkit.[43]

HUD notes that the 8-step decision making process for critical actions does require projects to consider ingress and egress along with alternative locations for the project with the intent of removing it from the floodplain if practicable.

HUD disagrees with the commenter that floodproofing fails to provide adequate flood mitigation for non-residential structures in the floodplain. HUD also notes that floodproofing can be done on any number of foundation types and does not require the use of poured concrete slabs. Additionally, HUD contends that CISA will provide a more realistic value for future risk than existing processes as it will address climate change over time. HUD disagrees that all development within the 1-percent-annual-chance floodplain should be forbidden so long as that development is subject to the requirements and protectiveness of a thorough evaluation through the 8-step decision making process.

2. Encouraging Use of Additional Resilience Strategies

Several commenters suggested a different set of strategies beyond elevation for substantial rehabilitation that would allow for more design upgrades to promote flood resiliency rather than elevating alone.

For example, some commenters recommended that HUD allow floodproofing to be used on residential buildings where there are units below the FFRMS floodplain. The commenters were concerned that the proposed rule could result in reducing the number of garden-style multifamily residential communities in urban locations that cannot comply with the elevation standards. The commenters went onto say that there are other ways such developments can support flood resiliency such as elevated machinery through design initiatives.

One commenter recommended that HUD consider the characteristics of the specific floodplain in addition to flood stage. The commenter said that elevation should incorporate evacuation planning, including evacuation prior to a flood event for resident and first responder safety.

Another commenter wrote to raise the importance of the International Code Council's model codes (''I-Codes''), which are developed in an open forum with a balance of interests represented and due process. The commenter strongly encouraged HUD to require numerous provisions within the I-Codes that provide flood mitigation benefits, including the latest International Residential Code and International Building Code, in order to ensure the most stringent flood provisions for federally assisted construction in flood zones and an enhanced level of resilience for both structures and communities. The commenter went on to emphasize that the National Institute of Building Sciences estimates that building to modern building codes saves $11 for every $1 invested (including earthquake, flood, and wind mitigation benefits) and retrofitting structures to current flood mitigation requirements can provide $6 in mitigation benefits for every $1 invested.

Another commenter supported the adoption of up-to-date modern building codes and standards and urged HUD to adopt the ASCE 7 Minimum Design Loads and Associated Criteria for Buildings and Other Structures, especially Chapter 5 Flood Loads.

HUD Response: HUD believes that floodproofing alone is insufficient to protect residents in the event of a flood and therefore does not allow floodproofing of residential units. HUD contends that units at high risk of flood loss are not safe and do not contribute to HUD's mission of providing safe affordable housing.

HUD appreciates the commenters' feedback regarding evacuation planning and notes that for critical actions, ingress and egress must be considered in the 8-step decision making process. HUD notes that additional hydrology characteristics of any individual floodplain and associated impacts should also be considered during the 8-step decision making process.

While HUD appreciates the efforts of the International Code Council, ASCE and others to increase building resilience and the importance of building codes generally, HUD currently has no intention of adding them into the part 55 requirements. HUD is separately coordinating with an interagency group in an effort to address building codes for HUD-assisted properties.

3. Opposition to Resiliency Requirements

One commenter suggested that because the proposed rule allows ''floodproofing'' instead of elevation, for example, for parking garages, it would cause individuals to potentially lose access to not only their homes but also their vehicles during a major weather event. This commenter suggested this

[43] Information on the Community Resilience Toolkit can be found here. *https://www.hudexchange.info/resource/5981/community-resilience-toolkit/.*

impact would fall on low-income communities, that the proposed rule doesn't craft more resilient livable locations, and that HUD should draw a firm line against ''floodproofing'' in the FFRMS floodplain for any new build.

Another commenter suggested that HUD's proposal unnecessarily expands floodplain management requirements and threatens access to FHA mortgage insurance programs for single family home buyers and multifamily builders. This commenter said that by establishing a higher flood risk standard, the proposed rule is inconsistent with NFIP and creates unwarranted and expansive flood mitigation requirements beyond those established by FEMA.

HUD Response: HUD disagrees with the commenter regarding the use of floodproofing on structures where all of the residential units are elevated above FFRMS. HUD maintains that floodproofing structures allows for resilient development that keeps residential structures out of riskier locations without significantly reducing the availability of land for construction. This is also in keeping with existing HUD regulations under part 55 which allow for the floodproofing of structures that do not have residential units below the floodplain elevation.

HUD disagrees that the rule unnecessarily expands floodplain management requirements. The increasing risk to housing structures and associated risks to human life posed by climate change are well documented. Under E.O. 11988, HUD is directed to protect the public's investment in housing and ensure a resilient housing stock. As such, HUD believes that increasing elevation standards for FHA backed new construction within the 1-percent-annual-chance floodplain is necessary in the Minimum Property Standards. As the Minimum Property Standards update is limited to the 1-percent-annual-chance floodplain, the horizontal extent of the floodplain of concern remains consistent with NFIP.

B. Use of Fill To Achieve Elevation Requirements

Several commenters were concerned about the use of fill within floodplains. Some commenters emphasized that the use of fill could redirect flood waters onto other properties with existing structures or otherwise cause expansion of the mapped floodplain elsewhere. One commenter worried this impact could lead local municipalities to decline to support FHA-financed projects. Another commenter was also concerned that the elevation requirements may cause cities and counties to reject development of HUD-insured or HUD-assisted housing if the sites are required to be elevated above neighboring sites.

Several commenters said that the proposed rule's floodproofing requirement for sites with no known or previously occurring flood risk will be prohibitively expensive. Some commenters noted it may result in reduced density allowable on the site to accommodate increased retention requirements and therefore a further reduction of property value. One commenter emphasized that elevation by fill has become common in the coastal plain of the Southeast and many communities have suffered worsening flooding and septic tank failures as a result of more water being pushed into their yards.

Several commenters suggested alternatives where fill is necessary to achieve elevation requirements, such as requiring that a project retain the volume of water onsite that is equivalent to the volume of fill used. Another commenter suggested that HUD should consider alternatives that would allow exceptions through which the local Floodplain Administrator may provide input on other design considerations for promoting flood resiliency; elevating residential structures above the FFRMS should not be the only option. Another commenter asked HUD to include guidance for how to remedy if neighboring properties are negatively impacted by improvements. Another commenter asked that HUD include what type of information would be needed to demonstrate runoff from a proposed development would not impact surrounding properties.

One commenter pointed out that using fill material to elevate structures will add significant cost to new construction including transport, earthwork, and compacting costs. Such an increase in costs, the commenter noted, might be passed onto low-income homeowners and renters.

Several commenters urged HUD to prohibit the use of fill to achieve elevation requirements altogether.

HUD Response: HUD agrees that use of fill within the floodplain can affect floodplain function. HUD notes that while the rule does increase elevation standards, it does not mandate the method by which elevation must be achieved. Under this rule, HUD would generally encourage grantees to use fill to elevate a site only where no other practicable alternative exists. Instead, HUD's preference is to elevate using methods that do not affect runoff of a site, such as piers or foundation walls. All project impacts, both on and offsite, must be addressed under the 8-step decision making process. It is up to the HUD or responsible entity environmental review preparer to propose mitigation measures which account for any impacts found during the 8-step decision making process though regional HUD staff may be able to provide technical assistance on a project-by-project basis.

According to the RIA, the cost of elevating and floodproofing structures is outweighed by the benefits of flood risk reduction and flood loss avoidance.

C. Cost and Feasibility of Elevation and Floodproofing Requirements

One commenter felt that HUD provided compelling data that the benefits of the proposed two-foot-above standard far exceed the costs, and without a standard, property owners would tend to under-insure and under-mitigate relative to the flood risk.

Another commenter argued, contrary to the proposed rule, that the cost of elevating properties is a financial burden to homeowners that would not be made up in saved insurance premiums. One commenter referenced HUD's RIA, which notes that the construction cost to elevate a new residential structure two feet does not pose a significant burden to small entities in the single family housing development industry and contended that more research is needed to come to that determination. The commenter cited one recent analysis that such costs are anywhere from $20,000–$80,000 and encouraged consideration of HUD's proposal to include the basement in the minimum elevation determination.

One commenter expressed their concern that one-story homeowners would not be able to reserve their only floor for a non-residential use to reduce their compliance costs and do not have the same flexibilities as builders to locate new projects outside floodplains.

One commenter noted that it is difficult to predict if the revised elevation standard is viable because land is forever shifting and changing, especially in wetlands.

Some commenters expressed their concern that requiring existing structures to elevate to 2-feet above the BFE may result in significant pushback from borrowers especially those associated with low-income housing transactions. These commenters were concerned that as a result, needed repairs and upgrades to low-income housing will not happen thus placing an undue burden on existing low-income housing.

Other commenters also expressed concern that it will be infeasible to

elevate an existing property to FFRMS elevation and so the inability to comply will leave housing stock in disrepair. Moreover, one commenter suggested that for the 40 percent of the U.S. population that resides in coastal communities—many of whom live in densely populated urban areas with limited alternative locations for development—raising a building several feet above BFE is not feasible. The commenter urged HUD to make exceptions where a building can be elevated above BFE but not as high as the FFRMS flood elevation.

One comment focused specifically on communities that may have restrictions on building heights for multifamily developments. Since, in those cases, the proposed rule's increased elevation requirements may result in a development exceeding building height requirements, this commenter urged HUD to work with FEMA to develop incentives within the ''Community Rating System'' for building additional stories on multifamily buildings located in floodplains instead of building horizontally. The commenter suggested that additional stories may be possible if they would increase a building's Community Rating System rating and result in cost savings to the community.

Several commenters asked for HUD to clarify how an existing multifamily structure with a basement could be practicably elevated above BFE.

HUD Response: HUD appreciates the commenters' feedback regarding the benefits and costs of the BFE+2 elevation standard. HUD's RIA determined that the cost of the increased elevation standard would be outweighed by the benefits of flood risk mitigation including flood loss avoidance and flood insurance cost reductions. HUD believes the RIA reflects the best available economic data on costs associated with flood insurance and flood risk.

HUD notes that per the rule, residential units will need to be elevated and not floodproofed for new construction and substantial improvement activities if they are located in the FFRMS floodplain. HUD disagrees that any potential changes in the land make it impossible to determine if the elevation standard is effective. HUD notes that non-residential floors can be floodproofed without elevation.

HUD contends that elevation and floodproofing of low-income housing is a needed repair or upgrade for these facilities, so funding spent on elevating and floodproofing these facilities is necessary. Any repairs that meet the threshold for substantial improvement as defined at § 55.2(b)(12) will trigger requirements for elevation. HUD does not currently have any plans to allow exceptions for buildings which can be elevated to BFE but not the FFRMS floodplain. HUD appreciates the feedback regarding populations living near the coasts as it highlights the need for the rule.

HUD notes that HUD funded projects must also be in compliance with local ordinances including those on height restrictions for design. Additionally, the Community Rating System is a function of NFIP regulations which fall under the purview of FEMA. HUD has no authority to grant incentives under the Community Rating System.

D. Strategies To Restore and Preserve Beneficial Values of Floodplains and Wetlands

Several commenters expressed support for HUD's commitment to nature-based floodplain management solutions through proposed § 55.20(e) and asked HUD to encourage projects to assess mitigation opportunities that restore natural floodplain and wetland functions proximate to project sites wherever practicable. One commenter expressed support for streamlining decision making for nature-based approaches.

Several commenters explained that nature-based approaches retain excess water and slowly release it back to natural drainage systems while improving water and air quality, recreational function, heat mitigation, and property aesthetics (citing FEMA and National Wildlife Federation research). One commenter described the strategies deployed for three successful nature-based mitigation projects of varying scope—a wetland and shoreline stabilization project, a creek restoration project in a residential and business development, and a stormwater resilience project in a flood-prone residential neighborhood. Several commenters reasoned that this rule's focus on nature-based solutions aligns with Federal adaptation strategy outlined in E.O. 14072, E.O. 13960, and the Biden-Harris Administration's Roadmap to Accelerate Nature-Based Solutions, encouraging HUD to use the Roadmap and its companion resource guide to further identify specific practices proven effective.

Several commenters encouraged HUD to include the following in mitigation guidance and training: (1) promote effectiveness of landscape-level practices encompassing the full property, including natural stormwater strategies (*e.g.,* bioswales, retention ponds); (2) provide a suite of strategies flexible to meet varying site-specific needs; and (3) encourage no- or low-adverse impact development practices.

Several commenters expressed support for HUD's efforts to better communicate the ecosystem services that natural systems provide through proposed § 55.20(e)(3), defining restoration and preservation of wetlands and the beneficial functions of floodplains. One commenter provided an Association of State Wetland Managers manual prepared for agency floodplain management staff and others to assess, protect, and restore floodplain ''natural and beneficial'' functions.

One commenter suggested that providing more details on the ecosystem services and economic benefits that wetlands and floodplains provide will increase public acceptance of the rule.

HUD Response: HUD appreciates commenters' support for the nature-based strategies identified in the new § 55.20(e). HUD encourages the use of nature-based solutions where practicable across its portfolio. HUD agrees that nature-based solutions provide significant benefits and ecosystem services to the floodplain and wetland areas in and around projects.

HUD not only encourages grantees to utilize nature-based solutions for floodplain management where possible, but § 55.20(e) requires the restoration and preservation of the natural and beneficial functions of the FFRMS floodplain where practicable. HUD believes these projects can provide significant value to both people in the built environment and the floodplain. Additionally, HUD strongly encourages floodways to be returned to greenspace when feasible.

HUD intends to provide guidance and technical assistance to grantees, applicants, and responsible entities to help them restore and preserve the natural and beneficial functions of the floodplain as part of their project. Additionally, HUD staff from the Office of Environment and Energy are available to help individual projects integrate mitigation into their projects.

E. Questions About Elevation and Floodproofing Requirements

Commenters asked HUD to confirm that the requirement for elevation of a site to or above a 0.2-percent-annual-chance floodplain with no known or previously occurring flood risk will not result in the requirement for completion of the 8-step decision making process before adding fill to modify a floodplain per section § 55.12(c)(8). If the 8-step decision making process would result, this commenter objects to the administrative burden it would place on

borrowers, lenders, and other stakeholders.

One commenter asked whether FHA Multifamily will allow lenders to avoid the FFRMS requirements and add risk to FHA by building with non-HUD funds and refinancing with FHA in a few years.

Some commenters noted that they did not understand the need to use a FEMA Elevation Certificate or FEMA Floodproofing Certificate to document elevations when CISA mapping is used because these tools are used in conjunction with FEMA maps rather than CISA maps.

Commenters also asked HUD to clarify what it means by ''by other means'' and ''from time to time'' when discussing documentation of elevation to avoid inconsistent or unequitable prescription of unknown data requirements.

Another commenter suggested HUD adopt the standard jointly developed by the Association of State Floodplain Managers, the USACE, and FM Approvals for floodproofing non-residential areas below the FFRMS floodplain elevation, which has existed for about 10 years and ensures that floodproofing products perform as designed and advertised.

HUD Response: The rule removes the exemption for LOMA/LOMR from § 55.12(c)(8). Additionally, LOMAs/LOMRs do not remove sites from the FFRMS floodplain. As such, sites within the FFRMS floodplain will be subject to part 55 including, potentially, a full 8-step decision making process. While HUD encourages local and State authorities to match HUD regulations where possible, HUD cannot regulate projects that fall outside the Federal nexus and do not receive HUD funding.

FEMA elevation certificates, floodproofing certificates, or other documentation as directed by HUD, provides the official elevation of structures. This elevation is necessary to compare structures with the FFRMS floodplain and determine if they are subject to part 55 and/or any elevation mitigation requirements. HUD programs must also follow any local or State requirements for documenting elevation if they exist. HUD notes that any documentation HUD directs the use of must at least meet the minimum elevation requirement of the FFRMS floodplain. HUD appreciates the commenter's thoughtful ideas and considerations for use of floodproofing standards; however, this rule requires alignment with FEMA's floodproofing standards at 44 CFR 60.3(c)(3)(ii) and 60.3(c)(4)(i).

The FHA Multifamily program strongly discourages lenders building with non-HUD funds and refinancing with FHA later to skirt HUD requirements as the FFRMS requirements under this rule are critical to protecting the safety of HUD-assisted residents and the long-term resilience of HUD investments.

F. Additional Recommendations for Elevation and Floodproofing Requirements

One commenter recommended that tested and certified engineered flood barriers be used for floodproofing, where applicable. This commenter also recommended that HUD amend its proposed rule to be effective for the ''lowest habitable'' floor of the building.

One commenter suggested that funding be provided via FEMA to provide low interest loans for house raising. The commenter noted the average cost of house raising is over $100,000.

One commenter recommended that HUD incorporate a requirement that parking areas be built to the BFE to ensure a consistent practice that can be anticipated by all stakeholders during project planning.

One commenter emphasized that the residents of communities impacted by floods possess a right of return consistent with human rights law that must be honored. The commenter said that such residents should be provided assistance in recovering via programs such as CDBG–DR.

One commenter recommended that HUD make it clear that elevation requirements apply to the new installation of manufactured housing. The commenter urged HUD to prioritize department-wide actions that increase climate resilience for manufactured housing, including facilitating public investments in flood adaptation projects that would protect manufactured housing, mandating stricter building codes including foundation anchoring standards, increasing access to Disaster Recovery funds, and creating incentives to move manufactured housing to safer sites outside of the FFRMS floodplain. Citing several studies, this commenter explained that manufactured and mobile homes have a higher risk of flooding than other housing types due to location and foundation types; and that natural disasters disproportionately adversely affect these residents due to limited legal protections, limited access to disaster relief, and higher poverty rates and mobility limitations.

One commenter encouraged HUD to implement enhanced construction standards consistently across its programs. The commenter said this would reduce complexity and increase programmatic efficiency.

One commenter recommended HUD exclude FHA multifamily mortgage insurance programs from the FFRMS and any elevation and/or flood proofing requirements outside of the 1-percent-annual-chance floodplain. This commenter pointed out that HUD's Office of Multifamily Housing already promotes resilience against flooding in the absence of a new FFRMS, and these changes, as well as State and local code requirements, increase resiliency for FHA-insured multifamily properties without the confusing and costly FFRMS requirements. This commenter urged HUD to defer to State and local governments to decide what resiliency measures are necessary and workable for multifamily developments in their communities, especially if those properties are not HUD-funded or HUD-assisted. This commenter reasoned that State and local governments typically adopt nationally recognized model codes, tailored to reflect local practices and needs, and that residences are built to these codes to withstand natural hazards while maintaining affordability.

HUD Response: HUD appreciates the commenter's thoughtful ideas and considerations for alteration of this section of the rule; however, currently, HUD has no plans to adopt any floodproofing or enhanced construction standards. Additionally, HUD does not intend to exclude FHA multifamily programs from FFRMS. HUD notes that HUD funded projects are required to comply with local and State regulations where they exceed the HUD minimum standards.

HUD notes that it has no control over FEMA's budget or funding program design. HUD also notes that CDBG–DR is funded through individual supplemental appropriations and, when available, grantees have broad discretion in determining how to use the funds. Homeowners that apply for CDBG–DR funding through grantee-run programs and are deemed ineligible for assistance are still welcome to fund their own repairs.

HUD does not believe that parking areas need to be built to BFE. While HUD would encourage projects to build outside of the 1-percent-annual-chance floodplain where practicable, HUD does not believe it is necessary to elevate parking lots.

HUD appreciates the commenters' request to make it clear that elevation requirements apply to the installation of new manufactured housing that is subject to part 55. HUD has historically interpreted the rule related to the

installation of new HUD-assisted MHUs to be equivalent to the building of new site-built homes under part 55. This would mean that elevation requirements for site-built homes also apply to MHUs subject to part 55. That being said, HUD has decided to revise the rule to clearly state that new siting and substantial improvements of MHUs are included in the part 55 definitions of new construction and substantial improvement, respectively. Additionally, HUD intends to provide subregulatory guidance and technical assistance focused on MHU elevation requirements. HUD also notes that facilitating public investments in flood adaptation projects that would protect manufactured housing, mandating stricter building codes including foundation anchoring standards, increasing access to Disaster Recovery funds, and creating incentives to move manufactured housing to safer sites outside of the FFRMS floodplain all fall outside the scope of this rulemaking.

As discussed earlier in this preamble, it is important to note that FHA-insured single family housing is not subject to part 55 and that FHA-insured single family manufactured housing is not subject to the 24 CFR 200.926d elevation standards of this final rule. Eligibility requirements, including elevation requirements, for FHA-insured manufactured housing can be found at 24 CFR part 3285: Manufactured Home Installation Standards and 24 CFR 203.43f: Eligibility of Mortgages Covering Manufactured Homes, as applicable, which are outside the scope of this rulemaking.

Existing Nonconforming Sites in § 55.21

Several commenters expressed general opposition towards HUD's proposed process for existing nonconforming sites. One commenter urged HUD to seriously consider disallowing construction and reconstruction within the floodway altogether. Another commenter remarked that § 55.21 appears to be a backdoor for HUD to continue subsidizing risky properties. This commenter felt that the provision was too vague and asked a number of questions such as: whether it will apply to buildings built in violation of NFIP or State, local, or Tribal law or ordinances; whether it will apply to buildings below the current FFRMS standard; how will financial risk be assessed for FHA projects; will it apply to hospitals and nursing homes; how will ingress and egress be analyzed; will HUD coordinate with first responders and emergency rescuers; will it apply to buildings with a history of flooding; how much staff time will it take to conduct this process and would that time be better used finding a safe site; whether HUD believes properties with improvements in floodways comply with the requirements of 24 CFR 5.703, especially paragraphs (a) and (f) and whether HUD is waiving 24 CFR 5.703 for applicable programs as well; and whether there is potential for greater litigation. The commenter said that this provision keeps the most vulnerable in harm's way and recommended it be removed from the final rule.

Several other commenters asked for clarity surrounding the process for existing nonconforming sites. One commenter said they found the change to § 55.21 confusing and asked whether the change means that HUD will continue to assist properties in the floodway in violation of its own regulations. Another commenter said the language of § 55.21(b) is confusing and potentially misleading and asked whether HUD would allow buildings with residential units to occupy the floodway as long as the individual units are out of the floodway or whether HUD will exclude buildings containing residential units from occupying the floodway. Additionally, this commenter asked how HUD will ensure building foundations that remain in the floodway are safe. Another commenter wanted clarity as to what stage HUD would be conducting a ''close look'' at the site to determine whether to continue assistance. This commenter was concerned that applicants will be reluctant to proceed with applications without assurance that HUD mortgage insurance will be possible. Other commenters asked whether HUD has examined its FHA and public housing portfolios to understand how many floodway projects will be subject to the ''very rare'' process. This commenter asked whether the alternative process would be used in lieu of oversight and whether any engineers or building science experts were involved in formulating this proposed provision.

Several other commenters supported the proposed provisions relating to existing nonconforming sites. One commenter wrote that they strongly believe that housing preservation and sustainability are complementary and that they recommend HUD pay particular attention to the preservation of existing affordable housing units and the buildings in which they reside. Another commenter welcomed HUD's proposal to address repeatedly flooded properties and urged HUD to pay close attention to repair and reconstruction of multifamily units and to prioritize new protections in communities where residents have been displaced, lost belongings, and required evacuation and rescue. This commenter emphasized that HUD should pay particular attention to communities where such existing structures are a significant portion of the affordable housing stock.

Several other commenters had recommendations for how to change or improve the existing nonconforming site process. One commenter recommended that the footprint of any building located in a FEMA floodway not be allowed to increase in size for rehabilitation purposes. This commenter also discouraged HUD from demolishing existing buildings and instead supported conducting detailed risk assessments to determine the viability of elevation, floodproofing, and relocation. Another commenter urged HUD to defer to NFIP or local regulations for actions within a floodway. Another commenter also suggested that an effective form of mitigation can be the implementation and enforcement of modern building codes for properties being rebuilt due to repetitive losses. Another commenter encouraged HUD to provide funding for buyouts with relocation assistance for properties experiencing repeated loss due to flood damage. This commenter supported HUD policies that increase resilience of existing housing stock but asked HUD to recognize that that is a short-term, temporary measure and that HUD should work towards the long-term goal of eliminating more housing in places at risk of flooding and erosion.

HUD Response: HUD appreciates the commenters' feedback regarding the updates to § 55.21. HUD intends to produce additional guidance and technical assistance to help provide context for when the exemption at § 55.21 should apply. Generally, HUD intends this alternative processing for existing nonconforming sites to be rarely authorized and only under limited circumstances. While HUD has not created an inventory of projects where this rule may be applicable, HUD is responsible for ensuring continued compliance with NEPA and part 55 via monitoring and other tracking mechanisms. HUD is also developing an internal dashboard for environmental review data that will provide additional information on project location and part 55 compliance over time. Regulatory rigidity can be useful in many circumstances but having limited flexibility to allow certain projects to receive necessary repairs/upgrades ensures that HUD avoids placing undue burdens on existing HUD-assisted or -insured housing.

HUD disagrees that this provision will keep the most vulnerable populations in harm's way. HUD contends that by requiring all residential units be removed from the floodway, completion of the 8-step decision making process, and incorporation of all practicable measures to meaningfully reduce flood risk and increase resilience, residents will be protected from future harm. HUD intends to review projects on a case-by-case basis and reserves the right to refuse to approve the project if it believes mitigation is inadequate to reduce the risk sufficiently for resident safety. This alternative processing for existing nonconforming sites is not intended to be used in lieu of oversight at any particular property and it should be noted that the NSPIRE inspection standards require grantees to ensure that all residents live in safe, habitable dwellings, and that the items and components located inside the building, outside the building, and within the units of HUD housing are to be functionally adequate, operable, and free of health and safety hazards.

HUD appreciates the commenter's sentiment that housing preservation and sustainability are inextricably linked and complimentary of one another. HUD also appreciates the feedback from the commenter regarding FEMA designated SRL properties, and HUD agrees that communities with a high percentage of SRL properties are worth particular attention. These properties represent some of the highest risk and HUD wishes to ensure any Federal investment is well protected.

HUD appreciates the commenter's thoughtful ideas and considerations for alteration of this section of the rule. HUD has revised the language of § 55.21 to provide additional clarity and to more explicitly state that all residential units are required to be removed from the floodway under this provision.

HUD does not expressly forbid the expansion of buildings in the floodway under § 55.21; however, any expansion would need to meet a strict set of minimum standards including no residential units, identified evacuation routes, a no-rise certification (as defined by FEMA), and elevation to the FFRMS floodplain. Additionally, HUD may impose any other requirements it deems necessary to ensure the safety of the structure and its occupants. HUD contends that while the section doesn't forbid construction, the requirements laid out will make it exceptionally difficult to expand a building in the floodway. The purpose of § 55.21 is to allow existing buildings to continue to provide safe housing to residents where no feasible alternatives currently exist. HUD notes that changes in local building codes or funding of additional buyout programs exist outside the scope of this rulemaking and require either local governance or acts of Congress to fund.

Minimum Property Standards for 1–4 Unit Residential Structures

Several commenters expressed support for the proposed elevation standards for the FHA Minimum Property Standards. One commenter predicted that the new standards would likely decrease flood losses for families who may be particularly impacted by flooding as they do not have the resources to respond or recover. Another commenter urged HUD to work with the White House Flood Resilience Interagency Working Group to monitor whether the new standard will adequately protect the structures in question. Another commenter supported the BFE plus two feet proposal but said that the 0.2-percent-annual-chance flood approach would be even better. Another commenter hoped that the new elevation standards would incentivize adoption of a freeboard standard matching the HUD Minimum Property Standard to ensure that all new development in special flood hazard areas will continue to qualify for FHA-insured mortgages. The commenter emphasized that such a result would have a tremendous positive impact on improving nationwide resilience to flooding.

One commenter supported the new standards but noted that they may be unachievable by certain properties such as row houses and small lots in high-cost areas where substantial improvements may be cost prohibitive especially for low and middle-income homeowners. This commenter went on to encourage HUD to look to a wider suite of mitigation measures in such circumstances, such as elevation of mechanical systems and installation of backwater valves, which can improve resilience while also being more cost effective. Additionally, this commenter noted that new elevation standards could impact building height limitations and recommended that the revised regulations acknowledge that building height may need to be measured on an appropriate reference plane that is not the ground surface to support resilient construction without putting undue restrictions on building height.

One commenter asked HUD to revise the proposed rule to make the standards for elevation consistent for site-built and manufactured homes. This commenter said that current NFIP standards measure the elevation of site-built homes from the bottom of the lowest floor but measure the elevation of manufactured homes from the bottom of the I-beam. The commenter noted that the space between the I-beam and the lowest floor in a manufactured home is usually used for insulation and duct work, which would be expensive to move versus the cost of the extra elevation of the home. The commenter did not see any evidence to support a higher BFE measurement for manufactured homes and said if the standards were more uniform, it would help manufactured home properties meet the BFE requirements.

One commenter pointed out that HUD's proposed rule speaks to substantial improvements but does not speak to requirements for repairs to homes that are substantially damaged by flooding. This commenter was concerned about the costs of elevating an existing home an additional two feet following substantial damage, especially given that NFIP's Increased Cost of Compliance coverage only provides up to $30,000 for such elevation. Another commenter also expressed concern that elevating a site may negatively impact adjoining sites as previously established draining patterns will be altered, which could lead to objections by local municipalities and rejection of FHA-financed projects.

Another commenter was concerned that even the new proposed Minimum Property Standards were inadequate. This commenter suggested that new construction within the floodplain should be avoided, and existing structures should be removed over time. The commenter went on to suggest that HUD's final rule also include an option or incentive for managed retreat from floodplains whereby new construction in a floodplain is prohibited, and once a HUD-funded property experiences a loss from flooding it should be given the opportunity for a buyout or a one-time replacement for existing loss plus a withdrawal of future Federal funding for the property. The commenter suggested that the managed retreat option is cost-effective, would reduce disaster loss and displacement of tenant and owners, and would improve tenant safety and the quality of floodplain function.

One commenter emphasized the need for a consistent Federal narrative on the required minimal development standard for constructing or insuring a structure with known flood risk, noting that the minimal standard for communities within an NFIP SFHA is the lowest floor at or above the BFE. This commenter was concerned about the potential for confusion if HUD changes its Minimum

Property Standards to two feet above BFE.

One commenter requested to see the proposed rule as it will be implemented—at least at 90 percent completion—prior to final publication in order to provide final comments.

HUD Response: HUD appreciates the commenter's feedback regarding the proposed elevation standards in the FHA Minimum Property Standards update. HUD agrees that updated standards should reduce flood losses for structures residing in the 1-percent-annual-chance floodplain. HUD intends to continually monitor this regulation along with all of its regulations to ensure they are having the intended impact. It should be noted that the update to the Minimum Property Standards elevation requirements is only regulated within the FEMA-mapped 1-percent-annual-chance floodplain and that the FFRMS floodplain requirements outlined in the part 55 update would not apply to FHA-insured single family mortgages.

HUD appreciates the commenters' feedback about properties where elevation may be difficult or infeasible. HUD contends these difficulties are present in only a limited number of structures substantially improved through FHA-insured loans which sit in the FEMA mapped 1-percent-annual-chance floodplain. To avoid this issue, HUD has removed elevation requirements for substantial improvement activities from the Minimum Property Standards update. While newly constructed units purchased with FHA-insured mortgages would still be subject to the elevation requirements, this change would alleviate much of the concern facing homeowners of existing structures which may need to undergo substantial improvements. HUD also contends that not all Federal programs fund the same types of projects; therefore, not all Federal agencies need to regulate to the same elevation requirements. HUD also notes that some programs, such as CDBG–DR, have already imposed higher elevation standards than the NFIP minimums for years. The increased elevation standard for FHA-insured single family new construction will increase the nation's resilient housing stock and help protect the communities that HUD serves.

Also, HUD notes that FHA-insured single family manufactured housing is not subject to part 55 or 24 CFR 200.926d elevation standards under the final rule. Flood elevation standards for FHA-insured manufactured housing can be found at 24 CFR 3285: Manufactured Home Installation Standards and 24 CFR 203.43f: Eligibility of Mortgages Covering Manufactured Homes, as applicable, and are outside the scope of this rulemaking.

Further, for both manufactured homes and stick-built homes subject to part 55, to determine the lowest floor, HUD looks to FEMA's regulations in 44 CFR 59.1 and FEMA's Elevation Certificate guidance or other applicable current FEMA guidance. For manufactured homes in A Zones, FEMA recommends measurement of MHU elevation from the I-beam as a best practice. HUD recommends following FEMA best practice where feasible. For manufactured homes in coastal high hazard areas (Zone V), FEMA requires measurement of MHU elevation from the bottom of the lowest horizontal structural member (*e.g.,* the I-beam).

HUD strongly disagrees that elevation inherently impacts drainage patterns on a given lot. HUD does not require elevation to be completed using any particular method and there are many methods that have no impact on the impervious surface or general slope of a lot. For example, homes may be elevated using pier and beam, knee wall, or crawl space construction methods.

While HUD appreciates the commenters' sentiment that new construction within a floodplain should be avoided, the need for new affordable housing nationwide can necessitate construction in these areas. HUD feels that a ban on new construction in all floodplain areas would have a significant impact on affordable housing availability. Instead, while HUD agrees that avoidance is generally preferred to mitigation, HUD also believes in resilient design and ensuring that construction which does occur is done with appropriate resilient measures. Managed retreat through buyout is an allowable option for local jurisdictions to utilize under existing rules. It should be noted that the rule is intended to incentivize floodplain restoration and preservation activities via an existing exemption from part 55 applicability for such activities. Funding and program eligibility for programs and projects focused on buyout or managed retreat fall outside the scope of this rulemaking and require changes to individual program regulations and/or Congressional funding acts to proceed.

HUD will not release an additional 90 percent draft proposal of the rule for public comment. HUD intends to continuously update and monitor all of its rules and regulations as it sees fit to ensure the continued pursuit of its missions and directives. This includes continued discussions with Federal interagency partners and the White House Flood Resilience Interagency Working Group that may provide useful outside perspectives on any shortcomings or limitations of existing regulations.

A. Question for Public Comment #7: Feedback on the Proposed FHA Single Family Minimum Property Standards

Several commenters supported HUD applying the same FHA single family Minimum Property Standards as were proposed in 2016.[44] One commenter wrote that existing HUD programs, such as CDBG–DR and FHA Multifamily programs, already demonstrate that higher elevation standards are practicable. Another commenter wrote that adopting FHA single family elevation standards consistent with what exists for the Multifamily and CDBG programs will increase equity. This commenter suggested that not expanding higher floodplain management standards across all HUD programs may exacerbate inequities and unacceptably suggest that residents of affordable housing must inevitably tolerate elevated flood risk.

Another commenter encouraged HUD to engage with additional scientific and model experts, home builders and developers, community officials, lenders, realtors, consumer groups, and other Federal agencies before changing how it determines which homes are subject to the Minimum Property Standards requirements. This commenter recognized that single family homes in many communities face the potential for increased severity and frequency of flooding events due to climate change but was concerned that more certainty around the proposed FFRMS floodplain approach is needed before major housing programs are impacted.

One commenter asked HUD to exempt FHA single family newly constructed and substantially improved structures located within the 1-percent-annual-chance (100-year) floodplain from any elevation and/or flood proofing requirements.

HUD Response: HUD appreciates the feedback received from commenters regarding changes to the Minimum Property Standards. While HUD agrees that higher standards can be more protective, HUD contends that they can also be more burdensome. HUD wishes to avoid creating an undue regulatory burden by creating too high a regulatory

[44] 81 FR 74967. In the 2016 proposed rule, the Minimum Property Standards would have relied on an FVA approach requiring elevation of new construction and substantial improvement to two feet above the base flood elevation.

floor through the Minimum Property Standards thereby potentially impacting the availability of affordable housing. HUD does not believe that FHA single-family newly constructed homes should be exempt from this rule. However, based on feedback received, HUD will require that the lowest floor be at least two feet above base flood elevation for new construction, as proposed, but will remove the requirement for elevation of substantially improved homes under the Minimum Property Standards. With this change, the elevation standard in this rule provides a substantial increase in protection without being unreasonably costly or creating an undue hardship on homeowners and builders as confirmed through the RIA and review of multiple alternatives to the rule.

Regulatory Impact Analysis

One commenter stated that HUD's RIA falls short of its mandate under E.O. 12866 because it does not analyze the most readily available alternative to this proposed rule, which is to raise the elevation standard one-foot-above instead of two. This commenter suggested HUD re-release the proposed rule with this analysis before publishing a final rule. Moreover, this commenter said that HUD also used a 2013 new construction study to calculate the costs of retrofitting existing homes, despite recognizing that the cost for substantial improvement projects is significantly higher than for new construction.

The same commenter suggested that HUD measured the proposed rule's benefits using the decreased insurance premiums from an outdated and inaccurate methodology that has been replaced by Risk Rating 2.0. Several other commenters also wrote in regarding FEMA's Risk Rating 2.0 program. One commenter requested that HUD support the reinstallation of flood insurance premium discounts for buildings mitigated through elevation or floodproofing within the Risk Rating 2.0 program. The commenter said these discounts are effective in driving mitigation to reduce flood risk and incentivize mitigation to at-risk buildings.

One commenter recommended that HUD conduct a study of the potential future impacts of implementing the new standards before issuing a final rule. This commenter expressed a lack of confidence in HUD's summary view that the impact is minimal in relation to the actual costs to elevate a home—particularly an existing home—under local building codes and Federal regulations. One commenter noted that the real-world impacts on individuals protected from flood related harms were not factored into the damage reduction found through HUD's regulatory impact analysis.

Another commenter noted that the Risk Rating 2.0 premium reductions for elevating properties should be more transparent. This commenter also noted HUD should consider working with FEMA to clarify financial benefits of elevating properties on flood insurance premiums. Following up on comments made during a listening event, another commenter stated that the expected 30 percent reduction in flood insurance described in the RIA resulting from building a home to base flood elevation plus one, is incorrect. The commenter also stated that HUD has not been transparent with the formula for calculating Risk Rating 2.0 pricing and so there is no easy way to determine if the 30 percent is accurate or inaccurate without obtaining full quotes. The commenter then attached multiple supporting documents that outline an example structure receiving flood insurance rate discounts for elevation that are lower than expected elevation discounts provided in the RIA.

One commenter requested more detailed information as to all aspects of the cost benefit analysis completed for the proposed rule that relate to the value of requiring flood coverage up to the full replacement cost of a building compared to a lesser degree of flood insurance. The commenter asked for more information regarding the value of full replacement cost coverage versus limiting the amount of flood insurance. Another commenter also requested more detail in the RIA (and in the FONSI) before a final rule is implemented. This commenter would like stakeholders to have access to CISA mapping, and clearer information as to when increased flood insurance requirements would apply.

Another commenter asked for clarification because the proposed rule states that CISA methodology would be the required methodology to define the FFRMS floodplain ''if HUD-approved maps are available''; however, the RIA describes the process as the developer being able to enter the project location, the anticipated life of the project, and the project criticality to generate an appropriate amount of climate-informed freeboard.

HUD Response: HUD disagrees with the commenter that the RIA falls short of meeting its mandate in E.O. 12866. According to the Mitigation Framework Leadership Group (MitFLG), BFE+2 is the recommended elevation height for Federal projects. This elevation standard provides a substantial increase in protection without being unreasonably costly or creating an undue hardship on homeowners and builders. The RIA reviewed multiple alternatives to the proposed rule and determined this was a viable option. The RIA used the best available data to make its determination. More recent peer reviewed studies utilizing FEMA's new Risk Rating 2.0 remain unavailable at time of writing and cannot be used to ascertain any better information. Given the unclear outlook of the future of Risk Rating 2.0, HUD felt it was prudent to leave out more recent, incomplete, and unvetted sources from its determination. HUD also notes that calculating damage loss avoidance can be difficult, particularly as it relates to human impacts.

HUD supports its Federal partners' efforts to increase the resilience of housing nationwide and believes that FEMA will have good cause to support any rating system used by NFIP. HUD has no direct authority over the management or implementation of elevation discounts for flood insurance policies. The discounts used in the RIA are based on the best available information and studies at the time of HUD's review. HUD has published all available information used in its decision making in the RIA attachment to the proposed and final rule. HUD encourages stakeholders to review CISA mapping tools as they become available from FEMA and NOAA and other Federal sources. Alternatively, HUD has revised the rule to clarify its position that it permits the voluntary use of formally adopted State, Tribal, and local CISA data, as described in § 55.7(f) and section II.B. of this preamble.

HUD intends to produce implementation guidance for grantees, applicants, and responsible entities to help them correctly utilize available tools to implement CISA. Additionally, HUD intends to provide technical assistance training to help grantees walk through particularly difficult cases.

V. Findings and Certifications

Regulatory Review—Executive Orders 12866, 13563, and 14094

Under E.O. 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. E.O. 13563 (Improving Regulations and Regulatory Review) directs Executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline,

expand, or repeal them in accordance with what has been learned.'' E.O. 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. E.O. 14094 (Modernizing Regulatory Review) amends section 3(f) of E.O. 12866, among other things. This final rule was determined to be a significant regulatory action under section 3(f) of Executive Order 12866 as amended by Executive Order 14094 but was not deemed to be significant under section 3(f)(1).

As discussed in this preamble, the regulatory amendments will, based on E.O. 13690 and the Guidelines, require, as part of the decision making process established to ensure compliance with E.O. 11988 (Floodplain Management), that new construction or substantial improvement in a floodplain be elevated above the FFRMS floodplain or floodproofed. HUD notes that E.O. 13690 amended E.O. 11988, Floodplain Management, which was originally issued in furtherance of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4001 *et seq.*); the Flood Disaster Protection Act of 1973, as amended (Pub. L. 93–234, 87 Stat. 975); and NEPA (42 U.S.C. 4321 *et seq.*). These amendments will also provide a process for determining the FFRMS floodplain that would establish a preference for the climate-informed science approach. This final rule also revises HUD regulations in various other ways, including permitting HUD assistance to be used for a broader range of reasonable activities in floodways and would allow improvements beyond maintenance at sites with onsite floodplains in exceptional circumstances, after completion of the 8-step decision making process. This final rule also revises HUD's Minimum Property Standards for one-to-four-unit housing to require that the lowest floor in newly constructed structures located within the 1-percent-annual-chance floodplain be built at least 2 feet above the base flood elevation. Additionally, this final rule also revises a categorical exclusion available when HUD performs the environmental review by making it consistent with changes to a similar categorical exclusion that is available to HUD grantees or other responsible entities when they perform the environmental review. Other changes clarify, streamline, and update HUD's regulations.

This final rule is part of HUD's commitment under HUD's Climate Action Plan. Building to the standards discussed in this final rule will increase resiliency, reduce the risk of flood loss, minimize the impact of floods on human safety, health, and welfare, and promote sound, sustainable, long-term planning informed by a more accurate evaluation of risk that considers possible sea level rise and increased development associated with population growth.

Regulatory Impact Analysis

Elevating HUD-assisted structures located in and around the FFRMS floodplain will lessen damage caused by flooding and avoid relocation costs to tenants associated with temporary moves when HUD-assisted structures sustain flood damage and are temporarily uninhabitable. These benefits, which are realized throughout the life of HUD-assisted structures, are offset by the one-time increase in construction costs, borne only at the time of construction.

In addition, the likelihood that floods in coastal areas will become more frequent and damaging due to rising sea levels in future decades necessitates a stricter standard than the one currently in place. Sea level along the contiguous U.S. coastline is expected to rise, on average, 10 to 12 inches (0.25 to 0.30 meters) over the next 30 years (2020 to 2050).[45] The Intergovernmental Panel on Climate Change (2019) also confirms that the sea level rise will continue throughout the 21st century.[46]

As discussed in the regulatory impact analysis (RIA) that accompanies this rule, HUD estimates that requiring developers to construct or floodproof HUD-funded or insured properties to two feet above base flood elevation for FHA-insured single family homes subject to part 200 and at or above the FFRMS floodplain for single and multi-family properties subject to part 55 will increase construction costs by $4.492 million to $85.036 million per annual cohort. These are one-time costs which occur at the time of construction. Benefits of the increased standard include avoided damage to buildings, as measured by decreased insurance premiums, and avoided costs associated with homeowners and tenants being displaced. These benefits occur annually over the life of the structures. Over a 40-year period, HUD estimates the net present value of aggregate benefits will total $56.4 million to $324.3 million for each annual cohort of new construction.

These estimates are based on the annual production and rehabilitation of HUD-assisted and insured structures in the floodplain and accounts for the 40 States (in addition to the District of Columbia and Puerto Rico) with existing freeboard requirements. The cost of compliance and expected benefits are lower in these States than in States that have no minimum elevation requirements above base flood elevation. HUD's analysis does not consider benefits due to further coastal sea level or riverine rise. Further increases in sea level rise or inland and riverine flooding would increase the benefits of this rule. For a complete description of HUD's analysis, please see the accompanying RIA for this rule on *regulations.gov.*

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities.

With respect to all entities, including small entities, it is unlikely that the economic impact would be significant. As the RIA explains, the benefits of reduced damage offset the construction costs. Further, small entities may benefit more since they are less likely to be able to endure financial hardships caused by severe flooding.

Based on an engineering study conducted for FEMA,[47] the construction cost of increasing the elevation of the base of a new residential structure two additional feet of vertical elevation varies from 0.3 percent to 4.8 percent of the base building cost. This results in an increase in the construction cost of a new house of up to $7,834 per single family home and $4,772 per unit of

[45] Sweet, W.V., B.D. Hamlington, R.E. Kopp, C.P. Weaver, P.L. Barnard, D. Bekaert, W. Brooks, M. Craghan, G. Dusek, T. Frederikse, G. Garner, A.S. Genz, J.P. Krasting, E. Larour, D. Marcy, J.J. Marra, J. Obeysekera, M. Osler, M. Pendleton, D. Roman, L. Schmied, W. Veatch, K.D. White, and C. Zuzak, 2022: Global and Regional Sea Level Rise Scenarios for the United States: Updated Mean Projections and Extreme Water Level Probabilities Along U.S. Coastlines. NOAA Technical Report NOS 01. National Oceanic and Atmospheric Administration, National Ocean Service, Silver Spring, MD, 111 pp., *https://oceanservice.noaa.gov/hazards/sealevelrise/sealevelrise-tech-report.html.*

[46] IPCC, 2019: Summary for Policymakers. In: IPCC Special Report on the Ocean and Cryosphere in a Changing Climate [H.-O. Poörtner, DC Roberts, V. Masson-Delmotte, P. Zhai, M. Tignor, E. Poloczanska, K. Mintenbeck, A. Alegría, M. Nicolai, A. Okem, J. Petzold, B. Rama, N.M. Weyer (eds.)]. In press.

[47] *See* Federal Emergency Management Agency, 2008 Supplement to the 2006 Evaluation of the National Flood Insurance Program's Building Standards (2013).

multifamily new construction for a multifamily property located in States with no existing freeboard requirements. Consequently, this would not pose a significant burden to small entities in the single family housing development industry.

These costs are likely higher than would be caused by the increased standards in this final rule because most HUD-assisted substantial improvement projects already involve elevation to comply with the current standard, elevation to the base flood elevation (base flood elevation +0). Thus, elevating a structure an additional two feet would be marginal compared to the initial cost of elevation to the floodplain level.

For these reasons, the undersigned certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Environmental Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available through the Federal eRulemaking Portal at *regulations.gov.* The FONSI is also available for public inspection during regular business hours in the Regulations Division, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, you must schedule an appointment in advance to review the FONSI by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Executive Order 13132, Federalism

E.O. 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either: (1) imposes substantial direct compliance costs on State and local governments and is not required by statute, or (2) preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Order. This rule does not have federalism implications and would not impose substantial direct compliance costs on State and local governments nor preempts State law within the meaning of the Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This rule does not impose any Federal mandates on any State, local, or Tribal governments, or on the private sector, within the meaning of UMRA.

Paperwork Reduction Act

The information collection requirements contained in this rule were reviewed by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB Control Number 2506–0151. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a valid control number.

List of Subjects

24 CFR Part 50

Environmental impact statements.

24 CFR Part 55

Environmental impact statements, Floodplains, Wetlands.

24 CFR Part 58

Community development block grants, Environmental impact statements, Grant programs—housing and community development, Reporting and recordkeeping requirements.

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social Security, Unemployment compensation, Wages.

For the reasons stated in this preamble, HUD amends 24 CFR parts 50, 55, 58, and 200 as follows:

PART 50—PROTECTION AND ENHANCEMENT OF ENVIRONMENTAL QUALITY

■ 1. The authority citation for part 50 is revised to read as follows:

Authority: 42 U.S.C. 3535(d) and 4321–4336e; and Executive Order 11991, 3 CFR, 1977 Comp., p.123.

§ 50.4 [Amended]

■ 2. Amend § 50.4 in paragraph (b)(2) by removing ''(3 CFR, 1977 Comp., p. 117)'' and adding in its place ''as amended by Executive Order 13690, February 4, 2015 (3 CFR, 2016 Comp., p. 268)''.

■ 3. Amend § 50.20 by revising paragraph (a)(2)(i) to read as follows:

§ 50.20 Categorical exclusions subject to the Federal laws and authorities cited in § 50.4.

(a) * * *

(2) * * *

(i) In the case of a building for residential use (with one to four units), the density is not increased beyond four units and the land use is not changed;

* * * * *

■ 4. Amend § 50.23 by revising paragraph (c) to read as follows:

§ 50.23 Public participation.

* * * * *

(c) All required notices shall be published in an appropriate local printed news medium or on an appropriate government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency. The required notices shall be sent to individuals and groups known to be interested in the proposed action.

* * * * *

PART 55—FLOODPLAIN MANAGEMENT AND PROTECTION OF WETLANDS

■ 5. The authority citation for part 55 is revised to read as follows:

Authority: 42 U.S.C. 3535(d), 4001–4128, and 5154a; 42 U.S.C. 4321 *et seq.;* E.O. 13690, 80 FR 6425; Pub. L. 93–234, 87 Stat. 975; E.O. 11988, 42 FR 26951, 3 CFR, 1977 Comp., p. 117; E.O. 11990, 42 FR 26961, 3 CFR, 1977 Comp., p 121.

■ 6. Amend § 55.1 by:

■ a. Revising the section heading;

■ b. In paragraph (a)(1), adding the text ''as amended,'' after ''Floodplain Management,'';

■ c. Revising paragraph (a)(3);

■ d. Removing paragraphs (a)(4) and (5);

■ e. Removing and reserving paragraph (b); and

■ f. Removing paragraph (c).

The revisions read as follows:

§ 55.1 Purpose.

(a) * * *

(3) This part implements requirements consistent with Executive

Order 11988, Floodplain Management, as amended, and Executive Order 11990, Protection of Wetlands, and employs the principles of the Unified National Program for Floodplain Management. These regulations apply to all proposed actions for which approval is required, either from HUD (under any applicable HUD program) or from a recipient (under programs subject to 24 CFR part 58), that are subject to potential harm by location in floodplains or wetlands. Covered actions include acquisition, construction, demolition, improvement, disposition, financing, and use of properties located in floodplains or wetlands.

* * * * *

■ 7. Revise and republish § 55.2 to read as follows:

§ 55.2 Terminology.

(a) With the exception of those terms defined in paragraph (b) of this section, the terms used in this part shall follow the definitions contained in section 6 of Executive Order 11988, section 7 of Executive Order 11990, and the ''Guidelines for Implementing Executive Order 11988, Floodplain Management, and Executive Order 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input''; the terms ''special flood hazard area,'' ''criteria,'' and ''Regular Program'' shall follow the definitions contained in FEMA regulations at 44 CFR 59.1; and the terms ''Letter of Map Revision'' and ''Letter of Map Amendment'' shall refer to letters issued by FEMA, as provided in 44 CFR part 65 and 44 CFR part 70, respectively.

(b) For purposes of this part, the following definitions apply:

(1) *Coastal high hazard area* means the area subject to high velocity waters, including but not limited to hurricane wave wash or tsunamis. The area is designated on a Flood Insurance Rate Map (FIRM) or Flood Insurance Study (FIS) under FEMA regulations, or according to best available information. (See § 55.8(b) for appropriate data sources.)

(2) *Compensatory mitigation* means the restoration (reestablishment or rehabilitation), establishment (creation), enhancement, and/or, in certain circumstances, preservation of aquatic resources for the purposes of offsetting unavoidable adverse impacts that remain after all appropriate and practicable avoidance and minimization have been achieved. Examples include, but are not limited to:

(i) *Permittee-responsible mitigation:* On-site or off-site mitigation undertaken by the holder of a wetlands permit under section 404 of the Clean Water Act (or an authorized agent or contractor), for which the permittee retains full responsibility;

(ii) *Mitigation banking:* A permittee's purchase of credits from a wetlands mitigation bank, comprising wetlands that have been set aside to compensate for conversions of other wetlands; the mitigation obligation is transferred to the sponsor of the mitigation bank; and

(iii) *In-lieu fee mitigation:* A permittee's provision of funds to an in-lieu fee sponsor (public agency or nonprofit organization) that builds and maintains a mitigation site, often after the permitted adverse wetland impacts have occurred; the mitigation obligation is transferred to the in-lieu fee sponsor.

(3)(i) *Critical action* means any activity for which even a slight chance of flooding would be too great, because such flooding might result in loss of life, injury to persons, or damage to property. Critical actions include activities that create, maintain or extend the useful life of those structures or facilities that:

(A) Produce, use or store highly volatile, flammable, explosive, toxic or water-reactive materials;

(B) Provide essential and irreplaceable records or utility or emergency services that may become lost or inoperative during flood and storm events (*e.g.,* community stormwater management infrastructure, water treatment plants, data storage centers, generating plants, principal utility lines, emergency operations centers including fire and police stations, and roadways providing sole egress from flood-prone areas); or

(C) Are likely to contain occupants who may not be sufficiently mobile to avoid loss of life or injury during flood or storm events, *e.g.,* persons who reside in hospitals, nursing homes, convalescent homes, intermediate care facilities, board and care facilities, and retirement service centers. Housing for independent living for the elderly is not considered a critical action.

(ii) Critical actions shall not be approved in floodways, LiMWAs, or coastal high hazard areas unless they meet an exception at § 55.8 or § 55.21.

(4) *Federal Flood Risk Management Standard (FFRMS) floodplain* means the floodplain as defined by Executive Order 13690 and the Guidelines for Implementing Executive Order 11988, Floodplain Management, and Executive Order 13690, Establishing a Federal Flood Risk Management Standard and a Process for Further Soliciting and Considering Stakeholder Input and further described as applied to HUD-assisted activities by § 55.7 of this part.

(5) *0.2-percent-annual-chance (500-year) floodplain* means the area, including the base flood elevation, subject to inundation from a flood having a 0.2 percent chance or greater of being equaled or exceeded in any given year. (See § 55.8(b) for appropriate data sources).

(6) *Floodway* means that portion of the floodplain which is effective in carrying flow, where the flood hazard is generally the greatest, and where water depths and velocities are the highest. The term ''floodway'' as used here is consistent with ''regulatory floodways'' as identified by FEMA. (See § 55.8(b) for appropriate data sources.)

(7) *Functionally dependent use* means a land use that must necessarily be conducted in close proximity to water (*e.g.,* a dam, marina, port facility, waterfront park, and many types of bridges).

(8) *High hazard area* means a floodway or a coastal high hazard area.

(9) *Impervious surface area* means an improved surface that measurably reduces the rate of water infiltration below the rate that would otherwise be provided by the soil present in a location prior to improvement, based on the soil type identified either by the Natural Resource Conservation Service Soil Survey or geotechnical study. Impervious surfaces include, but are not limited to, unperforated concrete or asphalt ground cover, unvegetated roofing materials, and other similar treatments that impede infiltration.

(10) *Limit of Moderate Wave Action (LiMWA)* means the inland limit of the portion of Coastal A Zone where wave heights can be between 1.5 and 3 feet during a base flood event, subjecting properties to damage from waves and storm surge. (See § 55.8(b) for appropriate data sources.)

(11) *1-percent-annual-chance (100-year) floodplain* means the area subject to inundation from a flood having a one percent or greater chance of being equaled or exceeded in any given year. (See § 55.8(b) for appropriate data sources.)

(12) *Substantial improvement*—(i) *Substantial improvement* means either:

(A) Any repair, reconstruction, modernization, or improvement of a structure, including a manufactured housing unit, the cost of which equals or exceeds 50 percent of the market value of the structure either:

(*1*) Before the improvement or repair is started; or

(*2*) If the structure has been damaged, and is being restored, before the damage occurred; or

(B) Any repair, reconstruction, modernization, or improvement of a structure, including a manufactured

housing unit, that results in an increase of more than twenty percent in the number of dwelling units in a residential project or in the average peak number of customers and employees likely to be on-site at any one time for a commercial or industrial project.

(ii) *Substantial improvement* may not be defined to include either:

(A) Any project for improvement of a structure to comply with existing state or local health, sanitary or safety code specifications that is solely necessary to assure safe living conditions, or

(B) Any alteration of a structure listed on the National Register of Historical Places or on a State Inventory of Historic Places.

(iii) Structural repairs, reconstruction, or improvements not meeting this definition are considered ''minor improvements''.

(13) *Wetlands* means those areas that are inundated or saturated by surface or ground water with a frequency sufficient to support, and under normal circumstances does or would support, a prevalence of vegetative or aquatic life that requires saturated or seasonally saturated soil conditions for growth and reproduction. Wetlands generally include swamps, marshes, bogs, and similar areas such as sloughs, prairie potholes, wet meadows, river overflows, mud flats, and natural ponds. This definition includes those wetland areas separated from their natural supply of water as a result of activities such as the construction of structural flood protection methods or solid fill roadbeds and activities such as mineral extraction and navigation improvements. This definition includes both wetlands subject to and those not subject to Section 404 of the Clean Water Act as well as constructed wetlands.

■ 8. Amend § 55.3 by:
■ a. Redesignating paragraphs (a) through (d) as paragraphs (b) through (e), respectively;
■ b. Add a new paragraph (a);
■ c. Revising newly redesignated paragraph (c)(1);
■ d. Removing the word ''technical'' from newly redesignated paragraph (c)(3);
■ e. Revising newly redesignated paragraphs (c)(4), (d), and (e); and
■ f. Adding paragraph (f).

The revisions and additions read as follows:

§ 55.3 Assignment of responsibilities.

(a) *General.* The implementation of Executive Orders 11988 and 11990 under this part shall be conducted by HUD for Department-administered programs subject to environmental review under 24 CFR part 50 and by authorized responsible entities that are responsible for environmental review under 24 CFR part 58.

* * * * *

(c) * * *

(1) Ensure compliance with this part for all actions under their jurisdiction that are proposed to be conducted, supported, or permitted in a floodplain or wetland, including taking full responsibility for all decisions made under their jurisdiction that are made pursuant to § 55.20 for environmental reviews completed pursuant to 24 CFR part 50;

* * * * *

(4) Incorporate in departmental regulations, handbooks, and project and site standards those criteria, standards, and procedures related to compliance with this part.

(d) *Responsible entity Certifying Officer.* Certifying Officers of responsible entities administering or reviewing activities subject to 24 CFR part 58 shall comply with this part in carrying out HUD-assisted programs. Certifying Officers shall monitor approved actions and ensure that any prescribed mitigation is implemented.

(e) *Grantees and applicants.* Grantees and Applicants that are not acting as responsible entities shall:

(1) Supply HUD (or the responsible entity authorized by 24 CFR part 58) with all available, relevant information necessary for HUD (or the responsible entity) to perform the compliance required by this part, including environmental review record documentation described in 24 CFR 58.38, as applicable;

(2) Implement mitigating measures required by HUD (or the responsible entity authorized by 24 CFR part 58) under this part or select alternate eligible property; and

(3) Monitor approved actions and ensure that any prescribed mitigation is implemented.

(f) *Third party providers.* Consultants and other parties to the environmental review process may prepare maps, studies (*e.g.,* hydraulic and hydrologic studies), and reports to support compliance with this part, including identification of floodplains and wetlands and development of alternatives or minimization measures. The following responsibilities, however, may not be delegated to the third-party provider:

(1) Receipt of public or agency comments;

(2) Selection or rejection of alternatives analyzed in Step 3 of the 8-step decision making process in § 55.20;

(3) Selection or rejection of minimization measures analyzed in Step 5 of the 8-step decision making process in § 55.20;

(4) Determination whether avoidance of floodplain or wetland impacts, according to the purpose of Executive Orders 11988 and 11990, is or is not practicable.

■ 9. Add §§ 55.4 through 55.6 to subpart A to read as follows:

Sec.

* * * * *

55.4 Notification of floodplain hazard.
55.5 Flood insurance.
55.6 Complying with this part.

§ 55.4 Notification of floodplain hazard.

(a) *Notification for property owners, buyers, and developers.* For actions in the FFRMS floodplain (as defined in § 55.7), HUD (or HUD's designee) or the responsible entity must ensure that any party participating in the transaction is notified that the property is in the FFRMS floodplain and whether flood insurance is required or available in this location. Notification shall also include a description of the approximate elevation of the FFRMS floodplain, proximity to flood-related infrastructure impacting the site including dams and levees, the location of ingress and egress or evacuation routes relative to the FFRMS floodplain, disclosure of information on flood insurance claims filed on the property to the extent available from FEMA, and other relevant information such as available emergency notification resources.

(b) *Renter notification.* For HUD-assisted, HUD-acquired, and HUD-insured rental properties within the FFRMS floodplain, new and renewal leases must include acknowledgements signed by residents indicating that they have been advised that the property is in a floodplain and flood insurance is available for their personal property. Notification shall also include the location of ingress and egress routes relative to the FFRMS floodplain, available emergency notification resources, and the property's emergency procedures for residents in the event of flooding.

(c) *Conveyance restrictions for the disposition of multifamily real property.* (1) In the disposition (including leasing) of multifamily properties acquired by HUD that are located in the FFRMS floodplain, the documents used for the conveyance must:

(i) Refer to those uses that are restricted under identified Federal, State, or local floodplain regulations; and

(ii) Include any land use restrictions limiting the use of the property by a

grantee or purchaser and any successors under State or local laws.

(2)(i) For disposition of multifamily properties acquired by HUD that are located in the FFRMS floodplain and contain critical actions, HUD shall, as a condition of approval of the disposition, require by covenant or comparable restriction on the property's use that the property owner and successive owners provide written notification to each current and prospective tenant concerning:

(A) The hazards to life and to property for those persons who reside or work in a structure located within the FFRMS floodplain, and

(B) The availability of flood insurance on the contents of their dwelling unit or business.

(ii) The notice described in paragraph (c)(2)(i) of this section shall also be posted in the building so that it will be legible at all times and easily visible to all persons entering or using the building.

§ 55.5 Flood insurance.

(a)(1) As required by section 102(a) of the Flood Disaster Protection Act of 1973, as amended (42 U.S.C. 4012a), when HUD financial assistance (including mortgage insurance) is proposed for acquisition or construction purposes in any special flood hazard area (as designated by the Federal Emergency Management Agency (FEMA) on an effective Flood Insurance Rate Map (FIRM) or Flood Insurance Study (FIS)), structures for which HUD financial assistance is provided must be covered by flood insurance in an amount at least equal to the project cost less estimated land cost, the outstanding principal balance of any HUD-assisted or HUD-insured loan, or the maximum limit of coverage available under the National Flood Insurance Program, whichever is least. Under section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), such proposed assistance in any special flood hazard area shall not be approved in communities identified by FEMA as eligible for flood insurance but which are not participating in the National Flood Insurance Program. This prohibition only applies to proposed HUD financial assistance in a FEMA-designated special flood hazard area one year after the community has been formally notified by FEMA of the designation of the affected area. This requirement is not applicable to HUD financial assistance in the form of formula grants to States, including financial assistance under the State-administered CDBG Program (24 CFR part 570, subpart I), Emergency Solutions Grant amounts allocated to States (24 CFR part 576), and HOME funds provided to a State under Title II of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12701–12839). HUD strongly encourages that flood insurance be obtained and maintained for all HUD-assisted structures in the FFRMS floodplain, sites that have previously flooded, or sites in close proximity to a floodplain.

(2) Under section 582 of the National Flood Insurance Reform Act of 1994 (42 U.S.C. 5154a), HUD disaster assistance that is made available in a special flood hazard area may not be used to make a payment (including any loan assistance payment) to a person for repair, replacement, or restoration of damage to any personal, residential, or commercial property if:

(i) The person had previously received Federal flood disaster assistance conditioned on obtaining and maintaining flood insurance; and

(ii) The person failed to obtain and maintain the flood insurance.

(b) HUD or the responsible entity may impose flood insurance requirements that exceed the minimums established by the Flood Disaster Protection Act of 1973 or by Tribal, State, or local requirements when needed to minimize financial risk from flood hazards. HUD and responsible entities have discretion to require that flood insurance be maintained for structures outside of the FEMA-mapped floodplain but within the FFRMS floodplain and/or that structures be insured up to the full replacement cost of the structure when needed to minimize financial risk from flood hazards. Nothing in this part limits additional flood insurance requirements that may be imposed by a mortgagee participating in a HUD assistance or mortgage insurance or guarantee program.

§ 55.6 Complying with this part.

(a) *Process.* The process to comply with this part is as follows:

(1) HUD or the responsible entity shall determine whether compliance with this part is required. Refer to § 55.12 for a list of activities that do not require further compliance with this part beyond the provisions of paragraph (c) of this section.

(2) HUD or the responsible entity shall refer to § 55.8 to determine whether the proposed action is eligible for HUD assistance or if it must be rejected as proposed.

(3) If the project requires compliance under this part and is not prohibited by § 55.8, HUD or the responsible entity shall refer to § 55.13 to determine whether the 8-step decision making process in § 55.20 is required.

(4) HUD or the responsible entity shall refer to § 55.10 to determine whether the 8-step decision making process in § 55.20 for wetland protection is required or whether best practices to minimize potential indirect impacts to wetlands should be pursued.

(5) HUD or the responsible entity shall determine whether an exception in § 55.14 applies that would allow them to complete an abbreviated decision-making process under § 55.20.

(6) Where the decision-making process is required, HUD or the responsible entity shall follow the decision-making process described in § 55.20, eliminating any steps as permitted under § 55.14.

(b) *Decision making.* HUD or the responsible entity shall determine whether to approve the action as proposed, approve the action with modifications or at an alternative site, or reject the proposed action, based on its analysis of the proposed risks and impacts. HUD or the responsible entity has discretion to reject any project where it determines that the level of flood hazard is incompatible with the proposed use of the site or that the extent of impacts to wetlands or to the beneficial function of floodplains is not acceptable, regardless of whether it would otherwise be acceptable under this part.

(c) *Other requirements.* Refer to §§ 55.4 and 55.5 to determine whether the proposed action may require notifications and/or flood insurance. Actions that do not require full compliance under this part may still trigger notification and flood insurance requirements.

(d) *Documentation.* HUD or the responsible entity shall require that all of the analysis required under this part, including applicable exceptions and all required steps described in § 55.20, be documented in the environmental review record.

Subpart B—Application of Executive Orders on Floodplain Management and Protection of Wetlands

■ 10. Add §§ 55.7 through 55.9 to read as follows:

Sec.

* * * * *

55.7 Identifying the FFRMS floodplain.

55.8 Limitations on HUD assistance in floodplains.

55.9 Identifying wetlands.

* * * * *

§ 55.7 Identifying the FFRMS floodplain.

(a) HUD or the responsible entity shall determine all compliance with the

floodplain review requirements of this part based on the FFRMS floodplain.

(b) For a non-critical action, HUD or the responsible entity shall define the FFRMS floodplain using the following process:

(1) The climate-informed science approach (CISA) to identify the area having an elevated flood risk during the anticipated life of the project if data is available and actionable. Data is available and actionable for a particular project where:

(i) The data can be accessed via a tool, resource, or other process developed or identified by a Federal agency or agencies to define the floodplain using the CISA, and

(ii) HUD has adopted the particular tool, resource, or other process through a **Federal Register** publication for comment.

(2) If CISA data is not available or actionable but FEMA has defined the 0.2-percent-annual-chance floodplain, those areas that FEMA has designated as within the 0.2-percent-annual-chance floodplain; or

(3) If neither CISA data nor FEMA-mapped 0.2-percent-annual-chance floodplain data is available, those areas that result from adding an additional two feet to the base flood elevation as established by the effective FIRM or FIS or—if available—FEMA-provided interim or preliminary maps or studies or advisory base flood elevations.

(4) FFRMS floodplain determinations under paragraphs (b)(2) and (3) of this section shall be made using the information provided in the latest FEMA resources. Elevation determinations based on CISA data or an interim or preliminary FEMA map cannot be used as a basis for a lower elevation than the base flood elevation on the current FIRM or FIS.

(c) For a critical action, the FFRMS floodplain is either:

(1) Those areas designated as having an elevated flood risk identified by the climate-informed science approach (CISA)—as determined based on the criticality of the action—during the anticipated life of the project if the data is available and actionable, as available and actionable is described in paragraph (b)(1) of this section; or

(2) If CISA data as described above is not available or actionable, an area either within the 0.2-percent-annual-chance floodplain or within the area that results from adding an additional three feet to the base flood elevation. The larger floodplain and higher elevation must be applied where the 0.2-percent-annual-chance floodplain is mapped. If FEMA resources do not map the 0.2-percent-annual-chance floodplain, the FFRMS floodplain is the area that results from adding an additional three feet to the base flood elevation based on best available information.

(3) FFRMS floodplain determinations under paragraph (c)(2) of this section shall be made using the information provided in the latest FEMA resources.

(d) If CISA data is not available or actionable and if FEMA FIRMS, FIS, preliminary maps or advisory base flood elevations are unavailable or insufficiently detailed to determine base flood elevation, other Federal, Tribal, State, or local data shall be used as ''best available information.'' If best available information is based only on past flooding and does not consider future flood risk:

(1) For non-critical actions, the FFRMS floodplain includes those areas that result from adding an additional two feet to the base flood elevation based on best available information.

(2) For critical actions, the FFRMS floodplain includes those areas that result from adding an additional three feet to the base flood elevation based on best available information.

(e) When preparing an Environmental Impact Statement (EIS), an analysis of the best available, actionable climate science, where available and actionable data exists or can be generated in accordance with 42 U.S.C. 4336(b)(3), as determined by HUD or the responsible entity, must be performed to define the FFRMS floodplain. These sources may supplement the FIRM or Advisory Base Flood Elevation (ABFE) in order to better minimize impacts to projects or to elevate or floodproof structures above the risk adjusted floodplain. These sources may not be used as a basis for a lower elevation than otherwise required under this section.

(f)(1) Regardless of whether HUD has adopted a particular tool, resource, or other process to define the floodplain using CISA, as described in paragraphs (b)(1) and (c)(1) of this section, HUD or a responsible entity may voluntarily define the FFRMS floodplain utilizing CISA when:

(i) A State, Tribal, or local government formally adopts, through code or other formal adoption measures, a tool, resource, or other written standard developed or utilized by the State, Tribal, or local government that provides data or other methods to identify the FFRMS floodplain using CISA for a particular project; or

(ii) HUD publishes guidance identifying a particular tool, resource, or other process that may be used to define the floodplain using CISA, and the tool, resource, or other process identified in the HUD-published guidance contains the necessary data or information to define the floodplain for the project being considered.

(2)(i) The approach in this paragraph (f) may not be used as a basis for a lower elevation than the lowest of:

(A) The 0.2-percent-annual-chance floodplain elevation;

(B) The elevation that results from adding an additional two feet to the base flood elevation; or

(C) The elevation required by paragraph (b) or (c) of this section, if CISA data is available and actionable under paragraph (b)(1) or (c)(1).

(ii) Where HUD or a responsible entity voluntarily defines the FFRMS floodplain using the options in paragraph (f)(1)(i) or (ii) of this section, the criticality of the action must be considered when determining the appropriate elevation of the FFRMS floodplain.

§ 55.8 Limitations on HUD assistance in floodplains.

(a) HUD financial assistance (including mortgage insurance) may not be approved with respect to:

(1) Any action located in a floodway unless one of the following applies:

(i) An exception listed in § 55.12 applies; or

(ii) A permanent covenant or comparable restriction will preserve all onsite FFRMS floodplain and/or wetland areas from future development or expansion of existing uses in the floodplain and/or wetland areas. Any rehabilitation, including reconstruction in the case of properties affected by Presidentially declared disasters, that does not expand the footprint of the buildings or the number of units on the site would be allowed within the FFRMS floodplain outside of the floodway. No buildings or improvements may modify or occupy the floodway, with the exception of:

(A) Functionally dependent uses (as defined in § 55.2(b)(7)) and utility lines;

(B) De minimis improvements, including minimal ground disturbance or placement of impervious surface area to ensure accessibility where this is permitted by local ordinances and does not increase flood risk to the property; or

(C) Buildings and improvements that will be removed as part of the proposed action.

(2) Any critical action located in a floodway, other than a functionally dependent use where any existing or new structure has been or will be elevated or floodproofed to the FFRMS elevation for critical actions; or any critical action in a coastal high hazard

area or LiMWA, other than a functionally dependent use where any existing or new structure has been or will be elevated and constructed in accordance with current FEMA V-zone construction standards at 44 CFR 60.3(e); provided that, for a critical action that is insurance of a mortgage on a property containing a floodway with no structures or improvements in the floodway, paragraph (a)(1) of this section applies; or

(3) Any noncritical action located in a coastal high hazard area, or LiMWA, unless the action is a functionally dependent use, is limited to existing structures or improvements, or is reconstruction following destruction caused by a Presidentially declared disaster. If the action is not a functionally dependent use, the action must be designed for location in a coastal high hazard area. An action will be considered designed for a coastal high hazard area if:

(i) In the case of reconstruction following destruction caused by a disaster, or substantial improvement, the work meets the current standards for V zones in FEMA regulations (44 CFR 60.3(e)) and, if applicable, the Minimum Property Standards for such construction in 24 CFR 200.926d(c)(4)(iii); or

(ii) In the case of existing construction (including any minor improvements that are not substantial improvements):

(A) The work met FEMA elevation and construction standards for a coastal high hazard area (or if such a zone or such standards were not designated, the 1-percent-annual-chance floodplain) applicable at the time the original improvements were constructed; or

(B) If the original improvements were constructed before FEMA standards for the 1-percent-annual-chance floodplain became effective or before FEMA designated the location of the action as within the 1-percent-annual-chance floodplain, the work would meet at least the earliest FEMA standards for construction in the 1-percent-annual-chance floodplain.

(b) All determinations made pursuant to this section shall be based on the effective FIRM or FIS unless FEMA has provided more current information. When FEMA provides interim flood hazard data, such as ABFE or preliminary maps and studies, HUD or the responsible entity shall use the latest of these sources. However, a base flood elevation from an interim or preliminary source cannot be used if it is lower than the base flood elevation on the current FIRM and FIS.

(c) Where HUD assistance is proposed for actions subject to § 55.20 on structures designated by FEMA as Severe Repetitive Loss (SRL) properties, and FEMA has approved measures that if implemented would qualify the property for a status of ''Mitigated'' as to the SRL list, HUD or the responsible entity will ensure that FEMA-identified mitigation measures are identified and implemented as part of the decision making process under § 55.20(e).

§ 55.9 Identifying wetlands.

The following process shall be followed in making the wetlands determination:

(a) HUD or the responsible entity shall determine whether the action involves new construction that is located in or impacts a wetland.

(b) As primary screening, HUD or the responsible entity shall verify whether the project area is located in proximity to wetlands identified on the National Wetlands Inventory (NWI) and assess the site for visual indication of the presence of wetlands such as hydrology (water), hydric soils, or wetland vegetation. Where the primary screening is inconclusive, potential wetlands should be further evaluated using one or more of the following methods:

(1) Consultation with the Department of the Interior, U.S. Fish and Wildlife Service (USFWS), for information concerning the location, boundaries, scale, and classification of wetlands within the area.

(2) Reference to the Department of Agriculture, Natural Resources Conservation Service (NRCS) National Soil Survey (NSS), and any Tribal, State, or local information concerning the location, boundaries, scale, and classification of wetlands within the action area and further site study by the environmental review preparer with reference to Federal guidance on field identification of the biological (rather than jurisdictional) characteristics of wetlands.

(3) Evaluation by a qualified wetlands scientist to delineate the wetland boundaries on site.

■ 11. Revise § 55.10 to read as follows:

§ 55.10 Limitations on HUD assistance in wetlands.

(a) When the proposed project includes new construction activities (including grading, clearing, draining, filling, diking, impounding, and related activities for any structure or facilities including the siting of new manufactured housing units) that will have a direct impact to onsite wetlands identified by the process described in § 55.9, compliance with this part requires completion of the 8-step decision making process in § 55.20 to address wetland impacts.

(b) When the proposed project may indirectly affect wetlands by modifying the flow of stormwater, releasing pollutants, or otherwise changing conditions that contribute to wetlands viability, the significance of these impacts must be evaluated and the impacts minimized through best management practices. If the project site includes wetlands that will not be impacted by new construction, HUD strongly encourages measures to preserve such wetlands from future impacts, including by obtaining a restrictive covenant, conservation easement, or other mechanism.

(c) When the proposed project may indirectly affect off-site wetlands, impacts should be minimized to the extent practicable. While this part does not require further decision making to address these effects under the authority of Executive Order 11990, measures to address offsite wetlands impacts may be necessary to comply with related laws and authorities including the Endangered Species Act or to address significant impacts under the National Environmental Policy Act.

§ 55.11 [Removed and Reserved]

■ 12. Remove and reserve § 55.11.

■ 13. Revise § 55.12 to read as follows:

§ 55.12 Inapplicability of 24 CFR part 55 to certain categories of proposed actions.

With the exception of the flood insurance requirements in § 55.5, this part shall not apply to the following categories of proposed HUD actions:

(a) HUD-assisted activities described in 24 CFR 58.34 and 58.35(b);

(b) HUD-assisted activities described in 24 CFR 50.19, except as otherwise indicated in § 50.19;

(c) The approval of financial assistance for restoring and preserving the natural and beneficial functions and values of floodplains and wetlands, including through acquisition of such floodplain and wetland property, where a permanent covenant or comparable restriction is placed on the property's continued use for flood control, wetland protection, open space, or park land, but only if:

(1) The property is cleared of all existing buildings and walled structures; and

(2) The property is cleared of related improvements except those which:

(i) Are directly related to flood control, wetland protection, open space, or park land (including playgrounds and recreation areas);

(ii) Do not modify existing wetland areas or involve fill, paving, or other

ground disturbance beyond minimal trails or paths; and

(iii) Are designed to be compatible with the beneficial floodplain or wetland function of the property.

(d) An action involving a repossession, receivership, foreclosure, or similar acquisition of property to protect or enforce HUD's financial interests under previously approved loans, grants, mortgage insurance, or other HUD assistance;

(e) Policy-level actions described at 24 CFR 50.16 that do not involve site-based decisions;

(f) A minor amendment to a previously approved action with no additional adverse impact on or from a floodplain or wetland;

(g) HUD's or the responsible entity's approval of a project site, an incidental portion of which is situated in the FFRMS floodplain (not including the floodway, LiMWA, or coastal high hazard area), but only if:

(1) The proposed project site does not include any existing or proposed buildings or improvements that modify or occupy the FFRMS floodplain except de minimis improvements such as recreation areas and trails; and

(2) The proposed project will not result in any new construction in or modifications of a wetland.

(h) Issuance or use of Housing Vouchers or other forms of rental subsidy where HUD, the awarding community, or the public housing agency that administers the contract awards rental subsidies that are not project-based (*i.e.,* do not involve site-specific subsidies);

(i) Special projects directed to the removal of material and architectural barriers that restrict the mobility of and accessibility to elderly and persons with disabilities.

■ 14. Add §§ 55.13 and 55.14 to read as follows:

§ 55.13 Inapplicability of 8-step decision making process to certain categories of proposed actions.

The decision-making process in § 55.20 shall not apply to the following categories of proposed actions:

(a) HUD's mortgage insurance actions and other financial assistance for the purchasing, mortgaging, or refinancing of existing one- to four-family properties in communities that are in the Regular Program of the National Flood Insurance Program (NFIP) and in good standing (*i.e.,* not suspended from program eligibility or placed on probation under 44 CFR 59.24), where the action is not a critical action and the property is not located in a floodway, coastal high hazard area, or LiMWA;

(b) Financial assistance for minor repairs or improvements on one- to four-family properties that do not meet the thresholds for ''substantial improvement'' under § 55.2(b)(12);

(c) HUD or a recipient's actions involving the disposition of individual HUD or recipient held one- to four-family properties;

(d) HUD guarantees under the Loan Guarantee Recovery Fund Program (24 CFR part 573), where any new construction or rehabilitation financed by the existing loan or mortgage has been completed prior to the filing of an application under the program, and the refinancing will not allow further construction or rehabilitation, nor result in any physical impacts or changes except for routine maintenance;

(e) The approval of financial assistance to lease an existing structure and/or units within an existing structure located within the floodplain, but only if;

(1) The structure is located outside the floodway or coastal high hazard area, and is in a community that is in the Regular Program of the NFIP and in good standing (*i.e.,* not suspended from program eligibility or placed on probation under 44 CFR 59.24);

(2) The project is not a critical action; and

(3) The entire structure is or will be fully insured or insured to the maximum extent available under the NFIP for at least the term of the lease.

(f) Special projects for the purpose of improving the energy or water efficiency of utilities or installing renewable energy that involve the repair, rehabilitation, modernization, weatherization, or improvement of existing structures or infrastructure, do not meet the thresholds for ''substantial improvement'' under § 55.2(b)(12), and do not include the installation of equipment below the FFRMS floodplain elevation; and

§ 55.14 Modified 5-step decision making process for certain categories of proposed actions.

The decision making steps in § 55.20(b), (c), and (g) (Steps 2, 3, and 7) do not apply to the following categories of proposed actions:

(a) HUD's or the recipient's actions involving the disposition of acquired multifamily housing projects or ''bulk sales'' of HUD-acquired (or under part 58 of recipients') one- to four-family properties in communities that are in the Regular Program of the NFIP and in good standing (*i.e.,* not suspended from program eligibility or placed on probation under 44 CFR 59.24). For programs subject to part 58, this paragraph applies only to recipients' disposition activities that are subject to review under part 58.

(b) HUD's actions under the National Housing Act (12 U.S.C. 1701 *et seq.*) for the purchase or refinancing of existing multifamily housing projects, hospitals, nursing homes, assisted living facilities, board and care facilities, and intermediate care facilities, in communities that are in good standing under the NFIP.

(c) HUD's or the recipient's actions under any HUD program involving the repair, rehabilitation, modernization, weatherization, or improvement of existing multifamily housing projects, hospitals, nursing homes, assisted living facilities, board and care facilities, intermediate care facilities, and one- to four-family properties, in communities that are in the Regular Program of the NFIP and are in good standing (*i.e.,* not suspended from program eligibility or placed on probation under 44 CFR 59.24), provided that the number of units is not increased more than 20 percent, the action does not involve a conversion from nonresidential to residential land use, the action does not meet the thresholds for ''substantial improvement'' under § 55.2(b)(12), and the footprint of the structure and paved areas is not increased by more than 20 percent.

(d) HUD's or the recipient's actions under any HUD program involving the repair, rehabilitation, modernization, weatherization, or improvement of existing nonresidential buildings and structures, in communities that are in the Regular Program of the NFIP and are in good standing (*i.e.,* not suspended from program eligibility or placed on probation under 44 CFR 59.24), provided that the action does not meet the thresholds for ''substantial improvement'' under § 55.2(b)(12) and the footprint of the structure and paved areas is not increased by more than 20 percent.

(e) HUD's or the recipient's actions under any HUD program involving the repair, rehabilitation, or replacement of existing nonstructural improvements including streets, curbs, and gutters, where any increase of the total impervious surface area of the facility is de minimis. This provision does not include critical actions, levee systems, chemical storage facilities (including any tanks), wastewater facilities, or sewer lagoons.

Subpart C—Procedures for Making Determinations on Floodplain Management and Protection of Wetlands

■ 15. Add § 55.16 to read as follows:

§ 55.16 Applicability of subpart C decision making process.

Table 1 to this section indicates the applicability, by location and type of action, of the decision making process for implementing Executive Order 11988 and Executive Order 11990 under this subpart.

TABLE 1 TO § 55.16

Type of proposed action (new reviewable action or an amendment) [1]	Floodways	Coastal high hazard and LiMWA areas	Wetlands or FFRMS floodplain outside coastal high hazard area, LiMWA area, and floodways
Critical actions as defined in § 55.2(b)(3).	Critical actions not allowed unless they meet the requirements for critical actions in § 55.8 and are processed under § 55.20 [2].	Critical actions not allowed unless they meet the requirements for critical actions in § 55.8 and are processed under § 55.20 [2].	Allowed if the proposed critical action is processed under § 55.20.[2]
Noncritical actions not excluded under § 55.12 or § 55.13.	Allowed only if the proposed non-critical action is not prohibited under § 55.8(a)(1) and is processed under § 55.20 [2].	Allowed only if the proposed noncritical action is processed under § 55.20 [2] and is (1) a functionally dependent use, (2) existing construction (including improvements), or (3) reconstruction following destruction caused by a disaster. If the action is not a functionally dependent use, the action must be designed for location in a coastal high hazard area under § 55.8(a)(3).	Allowed if proposed noncritical action is processed under § 55.20.[2]

[1] Under Executive Order 11990, the decision making process in § 55.20 only applies to Federal assistance for new construction in wetlands locations.

[2] Or those paragraphs of § 55.20 that are applicable to an action listed in § 55.14.

■ 16. Amend § 55.20 by:
■ a. Revising the introductory text, paragraph (a), paragraph (b) introductory text, and paragraphs (b)(1) and (2);
■ b. Removing ''HUD'' from the last sentence and adding in its place ''HUD's'' in paragraph (b)(3);
■ c. Adding paragraph (b)(4);
■ d. Revising paragraphs (c) introductory text, (c)(1)(i) and (ii), (c)(2) introductory text, (c)(2)(iii), (c)(3), (d) introductory text, (d)(1), (d)(2) introductory text, (d)(2)(i), (e), (f) introductory text, and (f)(2)(ii);
■ e. Adding paragraph (f)(2)(iii); and
■ f. Revising paragraph (g)(1) introductory text.

The revisions and additions read as follows:

§ 55.20 Decision making process.

Except for actions covered by § 55.14, the decision making process for compliance with this part contains eight steps, including public notices and an examination of practicable alternatives when addressing floodplains and wetlands. Third parties may provide analysis and information to support the decision making process; however, final determinations for each step, authorization of public notices, and receipt of public comments, are the responsibility of HUD or the responsible entity. The steps to be followed in the decision making process are as follows:

(a) *Step 1.* Using the processes described in §§ 55.7 and 55.9, determine whether the proposed action is located in the FFRMS floodplain or results in new construction that directly impacts an onsite wetland. If the action does not occur in the FFRMS floodplain or include new construction directly impacting an onsite wetland, then no further compliance with this section is required. Where the proposed action would be located in the FFRMS floodplain and includes new construction directly impacting an onsite wetland, these impacts should be evaluated together in a single 8-step decision making process. In such a case, the wetland will be considered among the primary natural and beneficial functions and values of the floodplain. For purposes of this section, an ''action'' includes areas required for ingress and egress, even if they are not within the site boundary, and other integral components of the proposed action, even if they are not within the site boundary.

(b) *Step 2.* Notify the public and agencies responsible for floodplain management or wetlands protection at the earliest possible time of a proposal to consider an action in an FFRMS floodplain or wetland and involve the affected and interested public and agencies in the decision making process.

(1) The public notices required by paragraphs (b) and (g) of this section may be combined with other project notices wherever appropriate. Notices required under this part must be bilingual or multilingual, as appropriate, if the affected public has Limited English Proficiency. In addition, all notices must be published in a newspaper of general circulation in the affected community or on an appropriate government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency, and must be sent to Federal, State, and local public agencies, organizations, and, where not otherwise covered, individuals known to be interested in the proposed action.

(2) A minimum of 15 calendar days shall be allowed for comment on the public notice. The first day of a time period begins at 12:01 a.m. local time on the day following the publication or the mailing and posting date of the notice which initiates the time period.

* * * * *

(4) When the proposed activity is located in or affects a community with environmental justice concerns, public comment and decision making under this part shall be coordinated with consultation and decision making under HUD policies implementing 24 CFR 58.5(j) or 50.4(l).

(c) *Step 3.* Identify and evaluate practicable alternatives to locating the proposed action in the FFRMS floodplain or wetland.

(1) * * *

(i) Locations outside and not affecting the FFRMS floodplain or wetland;

(ii) Alternative methods to serve the identical project objective, including but not limited to design alternatives such as repositioning or reconfiguring proposed siting of structures and improvements or incorporating natural systems, ecosystem processes, and nature-based solutions to avoid floodplain and wetland impacts; and

* * * * *

(2) Practicability of alternatives should be addressed in light of the goals identified in the project description related to the following:

* * * * *

(iii) Economic values such as the cost of space, construction, services, relocation, potential property losses from flooding, and cost of flood insurance.

(3) For multifamily and healthcare projects involving HUD mortgage insurance that are initiated by third parties, HUD in its consideration of practicable alternatives is not required to consider alternative sites, but must include consideration of:

(i) A determination to approve the request without modification;

(ii) A determination to approve the request with modification; and

(iii) A determination not to approve the request.

(d) *Step 4.* Identify and evaluate the potential direct and indirect impacts associated with the occupancy or modification of the FFRMS floodplain or the wetland and the potential direct and indirect support of floodplain and wetland development that could result from the proposed action, including impacts related to future climate-related flood levels, sea level rise, and the related increased value of beneficial floodplain and wetland functions.

(1) *Floodplain evaluation.* The floodplain evaluation for the proposed action must evaluate floodplain characteristics (both existing and as proposed for modification by the project) to determine potential adverse impacts to lives, property, and natural and beneficial floodplain values as compared with alternatives identified in Step 3.

(i) Floodplain characteristics include:

(A) Identification of portions of the site that are subject to flood risk, documented through mapping and, as required by § 55.7(e) or commensurate with the scale of the project and available resources as permitted by § 55.7(f), climate-informed analysis of factors including development patterns, streamflow, and hydrologic and hydraulic modeling;

(B) Topographic information that can inform flooding patterns and distance to flood sources, as described in flood mapping, Flood Insurance Studies, and other data sources; and

(C) Public safety communications and data related to flood risk including available information on structures such as dams, levees, or other flood protection infrastructure located in proximity to the site.

(ii) Impacts to lives and property include:

(A) Potential loss of life, injury, or hardship to residents of the subject property during a flood event;

(B) Damage to the subject property during a flood event;

(C) Damage to surrounding properties from increased runoff or reduction in floodplain function during a flood event due to modification of the subject site;

(D) Health impacts due to exposure to toxic substance releases that may be caused or exacerbated by flood events; and

(E) Damage to a community as a result of project failure (*e.g.,* failure of stormwater management infrastructure due to scouring).

(iii) Impacts to natural and beneficial values include changes to:

(A) Water resources such as natural moderation of floods, water quality maintenance, and groundwater recharge;

(B) Living resources such as flora and fauna (if the project requires consultation under 24 CFR 50.4(e) or 58.5(e), consultation with the U.S. Fish and Wildlife Service or National Marine Fisheries Service must include a description of impacts evaluated under this part);

(C) Cultural resources such as archaeological, historic, aesthetic and recreational aspects; and

(D) Agricultural, aquacultural, and forestry resources.

(2) *Wetland evaluation.* In accordance with section 5 of Executive Order 11990, the decision maker shall consider factors relevant to a proposal's effect on the survival and quality of the wetland. Factors that must be evaluated include, but are not limited to:

(i) Public health, safety, and welfare, including water supply, quality, recharge, and discharge; pollution; flood and storm hazards and hazard protection; and sediment and erosion, including the impact of increased quantity or velocity of stormwater runoff on, or to areas outside of, the proposed site;

* * * * *

(e) *Step 5.* Where practicable, design or modify the proposed action to minimize the potential adverse impacts to and from the FFRMS floodplain or wetland and to restore and preserve their natural and beneficial functions and values.

(1) *Elevation.* For actions in the FFRMS floodplain, the required elevation described in this section must be documented on an Elevation Certificate or a Floodproofing Certificate in the Environmental Review Record prior to construction, or by such other means as HUD may from time to time direct, provided that notwithstanding any language to the contrary, the minimum elevation or floodproofing requirement for new construction or substantial improvement actions shall be the elevation of the FFRMS floodplain as defined in this section.

(i) If a residential structure undergoing new construction or substantial improvement is located in the FFRMS floodplain, the lowest floor or FEMA-approved equivalent must be designed using the elevation of the FFRMS floodplain as the baseline standard for elevation, except where higher elevations are required by Tribal, State, or locally adopted code or standards, in which case those higher elevations apply. Where non-elevation standards such as setbacks or other flood risk reduction standards that have been issued to identify, communicate, or reduce the risks and costs of floods are required by Tribal, State, or locally adopted code or standards, those standards shall apply in addition to the FFRMS baseline elevation standard.

(ii) New construction and substantial improvement of residential structures that have no dwelling units below the FFRMS floodplain and that are not critical actions as defined at § 55.2(b)(3), or of non-residential structures, shall be designed either:

(A) With the lowest floor, including basement, elevated to or above the elevation of the FFRMS floodplain; or

(B) With the structure floodproofed at least up to the elevation of the FFRMS floodplain. Floodproofing standards are as stated in FEMA's regulations at 44 CFR 60.3(c)(3)(ii) and (c)(4)(i), or such other regulatory standard as FEMA may issue, and applicable guidance, except that where the standard refers to base flood level, floodproofing is required at or above the FFRMS floodplain, as defined in this part.

(iii) The term ''lowest floor'' must be applied consistent with FEMA regulations in 44 CFR 59.1 and FEMA's Elevation Certificate guidance or other applicable current FEMA guidance.

(2) *Minimization.* Potential harm to or within the floodplain and/or wetland must be reduced to the smallest possible amount. E.O. 11988's requirement to minimize potential harm applies to the

investment at risk or the flood loss potential of the action itself, the impact the action may have on others, and the impact the action may have on floodplain and wetland values. The record must include a discussion of all minimization techniques that will be incorporated into project designs as well as those that were considered but not approved. Minimization techniques for floodplain and wetlands purposes include, but are not limited to:

(i) *Stormwater management and green infrastructure:* The use of permeable surfaces; natural landscape enhancements that maintain or restore natural hydrology through infiltration, native plant species, bioswales, rain gardens, or evapotranspiration; stormwater capture and reuse; green or vegetative roofs with drainage provisions; WaterSense products; rain barrels and grey water diversion systems; protective gates or angled safety grates for culverts and stormwater drains; and other low impact development and green infrastructure strategies, technologies, and techniques. Where possible, use natural systems, ecosystem processes, and nature-based approaches when developing alternatives for consideration.

(ii) *Adjusting project footprint:* Evaluate options to relocate or redesign structures, amenities, and infrastructure to minimize the amount of impermeable surfaces and other impacts in the FFRMS floodplain or wetland. This may include changes such as designing structures to be taller and narrower or avoiding tree clearing to reduce potential erosion from flooding.

(iii) *Resilient building standards:* Consider implementing resilient building codes or standards to ensure a reliable and consistent level of safety.

(iv) *Severe Repetitive Loss (SRL) mitigation:* Identify and incorporate FEMA identified SRL mitigation as outlined in § 55.8(c), if applicable.

(3) *Restoration and preservation.* Restore means to reestablish a setting or environment in which the natural and beneficial values of floodplains and wetlands could again function. Where floodplain and wetland values have been degraded by past actions, restoration is informed by evaluation of the impacts of such actions on beneficial values of the floodplain or wetland and identification, evaluation, and implementation of practicable measures to restore the values diminished or lost. Preserve means to prevent modification to the natural floodplain or wetland environment or to maintain it as closely as possible to its natural state. If an action will result in harm to or within the floodplain or wetland, HUD or the responsible entity must ensure that the action is designed or modified to assure that it will be carried out in a manner which preserves as much of the natural and beneficial floodplain and values as is possible. Restoration and preservation techniques for floodplain and wetlands purposes include, but are not limited to:

(i) Natural Resource Conservation Service or other conservation easements;

(ii) Appropriate and practicable compensatory mitigation, which is required for unavoidable adverse impacts to more than one acre of wetlands. Compensatory mitigation includes but is not limited to: permittee-responsible mitigation, mitigation banking, in-lieu fee mitigation, the use of preservation easements or protective covenants, and any form of mitigation promoted by State or Federal agencies. The use of compensatory mitigation may not substitute for the requirement to avoid and minimize impacts to the maximum extent practicable.

(4) *Planning for residents' and occupants' safety.* (i) For multifamily residential properties and residential healthcare facilities, an evacuation plan must be developed that includes safe egress route(s) out of the FFRMS floodplain, plans for evacuating residents with special needs, and clear communication of the evacuation plan and safety resources for residents.

(ii) For all healthcare facilities, evacuation route(s) out of the FFRMS floodplain must be identified and clearly communicated to all residents and employees. Such actions must include a plan for emergency evacuation and relocation to a facility of like capacity that is equipped to provide required critical needs-related care and services at a level similar to the originating facility.

(iii) All critical actions in the FFRMS floodplain must operate and maintain an early warning system that serves all facility occupants.

(f) *Step 6.* HUD or the responsible entity shall consider the totality of the previous steps and the criteria in this section to make a decision as to whether to approve, approve with modifications, or reject the proposed action. Adverse impacts to floodplains and wetlands must be avoided if there is a practicable alternative. This analysis must consider:

* * * * *

(2) * * *

(ii) A reevaluation of alternatives under this step should include a discussion of economic costs. For floodplains, the cost estimates should include savings or the costs of flood insurance, where applicable; flood proofing; replacement of services or functions of critical actions that might be lost; and elevation to at least the elevation of the FFRMS floodplain, as appropriate based on the applicable source under § 55.7. For wetlands, the cost estimates should include the cost of filling the wetlands and mitigation.

(iii) If the proposed activity is located in or affects a community with environmental justice concerns, the reevaluation must address public input provided during environmental justice outreach, if conducted, and must document the ways in which the activity, in light of information analyzed, mitigation measures applied, and alternatives selected, serves to reduce any historical environmental disparities related to flood risk or wetlands impacts in the community.

(g) * * *

(1) If the reevaluation results in a determination that there is no practicable alternative to locating the proposal in the FFRMS floodplain or the wetland, publish a final notice that includes:

* * * * *

■ 17. Revise § 55.21 to read as follows:

§ 55.21 Alternate processing for existing nonconforming sites.

Notwithstanding the limitations on HUD assistance defined in § 55.8, in exceptional circumstances, the Assistant Secretary for Community Planning and Development may approve HUD assistance or insurance to improve an existing property with ongoing HUD assistance or mortgage insurance if the following conditions are satisfied:

(a) HUD completes an environmental review pursuant to 24 CFR part 50, including the 8-step decision making process pursuant to § 55.20, that:

(1) Documents that it is not practicable to transfer the HUD assistance to a site with lower flood risk under existing program rules, financial limitations, and site availability; and

(2) Mandates measures to ensure that the elevated flood risk is the only environmental hazard or impact that does not comply or that requires mitigation to comply, with HUD's environmental requirements at 24 CFR parts 50, 51, 55, and 58; and

(b) The proposed project incorporates all practicable measures to minimize flood risk, preserve the function of the floodplain and any impacted wetlands as described in § 55.20(e), and increase the overall resilience of the site, as approved and/or required by HUD. At minimum, these measures must include:

(1) Removal of all residential units and critical action structures from the floodway;

(2) Identification of evacuation routes out of the FFRMS floodplain;

(3) A No-Rise Certification for any new improvements in the floodway; and

(4) Elevation (or floodproofing pursuant to § 55.20(e)(1)) of existing structures within the FFRMS Floodplain, where practicable.

§§ 55.22, 55.24, and 55.25 [Removed and Reserved]

■ 18. Remove and reserve §§ 55.22, 55.24, and 55.25.

■ 19. Amend § 55.26 by revising the section heading, the introductory text, and paragraphs (b)(1) and (c) to read as follows:

§ 55.26 Adoption of another agency's review under the Executive orders.

If a proposed action covered under this part is already covered in a prior review performed under Executive Order 11988 or Executive Order 11990 by another agency, including HUD or a different responsible entity, that review may be adopted by HUD or by a responsible entity authorized under 24 CFR part 58 without further public notice, provided that:

* * * * *

(b) * * *

(1) The action currently proposed has not substantially changed in project description, scope, and magnitude from the action previously reviewed by the other agency; and

* * * * *

(c) HUD assistance must be conditioned on mitigation measures prescribed in the previous review.

§§ 55.27 and 55.28 [Removed]

■ 20. Remove §§ 55.27 and 55.28.

■ 21. Add subpart D, consisting of § 55.30, to read as follows:

Subpart D—Severability

§ 55.30 Severability.

Any provision of this part held to be invalid or unenforceable as applied to any action should be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding is that the provision of this part is invalid and unenforceable in all circumstances, in which event the provision should be severable from the remainder of this part and shall not affect the remainder thereof.

PART 58—ENVIRONMENTAL REVIEW PROCEDURES FOR ENTITIES ASSUMING HUD ENVIRONMENTAL REVIEW RESPONSIBILITIES

■ 22. The authority citation for part 58 is revised to read as follows:

Authority: 12 U.S.C. 1707 note, 1715z–13a(k); 25 U.S.C. 4115 and 4226; 42 U.S.C. 1437x, 3535(d), 3547, 4321–4336e, 4852, 5304(g), 12838, and 12905(h); title II of Pub. L. 105–276; E.O. 11514 as amended by E.O. 11991, 3 CFR, 1977 Comp., p. 123.

■ 23. Amend § 58.5 by revising paragraph (b)(1) to read as follows:

§ 58.5 Related Federal laws and authorities.

* * * * *

(b) * * *

(1) Executive Order 11988, Floodplain Management, as amended by Executive Order 13690, February 4, 2015 (3 CFR, 2016 Comp., p. 268), as implemented in HUD regulations at 24 CFR part 55, particularly section 2(a) of Executive Order 11988, as amended.

* * * * *

§ 58.43 [Amended]

■ 24. Amend § 58.43 in paragraph (a) by:

■ a. Removing ''tribal, local, State and Federal agencies;'' and add in its place ''Tribal, Federal, State, and local agencies''; and

■ b. Adding ''or on an appropriate Government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency'' after ''affected community'' in the third sentence.

■ 25. Revise and republish § 58.45 to read as follows:

§ 58.45 Public comment periods.

Required notices must afford the public the following minimum comment periods, counted in accordance with § 58.21:

(a) Notice of Finding of No Significant Impact (FONSI).	15 days when published in a general circulation newspaper or on a Government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency or, if no publication, 18 days when mailing and posting.
(b) Notice of Intent to Request Release of Funds (NOI–RROF).	7 days when published in a general circulation newspaper or on a Government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency or, if no publication, 10 days when mailing and posting.
(c) Concurrent or combined notices	15 days when published in a general circulation newspaper or on a Government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency or, if no publication, 18 days when mailing and posting.

§ 58.59 [Amended]

■ 26. Amend § 58.59 in paragraph (b) introductory text by adding ''or on an appropriate government website that is accessible to individuals with disabilities and provides meaningful access for individuals with Limited English Proficiency'' after ''news media''.

PART 200—INTRODUCTION TO FHA PROGRAMS

■ 27. The authority citation for part 200 continues to read as follows:

Authority: 12 U.S.C. 1702–1715z-21; 42 U.S.C. 3535(d).

■ 28. Amend § 200.926d by

■ a. Revising paragraphs (c)(4)(i) through (iii);

■ b. Removing paragraph (c)(4)(iv); and

■ c. Redesignating paragraphs (c)(4)(v) and (vi) as paragraphs (c)(4)(iv) and (v), respectively.

The revisions read as follows:

§ 200.926d Construction requirements.

* * * * *

(c) * * *

(4) * * *

(i) *Residential structures located in Special Flood Hazard Areas.* The elevation of the lowest floor (including basements and other permanent enclosures) shall be at least two feet above the base flood elevation (see 24 CFR 55.8(b) for appropriate data sources).

(ii) *Residential structures located in FEMA-designated ''coastal high hazard areas.''* Where FEMA has determined the base flood level without establishing stillwater elevations, the bottom of the lowest structural member of the lowest floor (excluding pilings and columns) and its horizontal supports shall be at least two feet above the base flood elevation.

(iii) *New construction.* (A) In all cases in which a Direct Endorsement (DE) mortgagee or a Lender Insurance (LI) mortgagee seeks to insure a mortgage on a one- to four-family dwelling that is newly constructed (including a newly

erected manufactured home) that was processed by the DE or LI mortgagee, the DE or LI mortgagee must determine whether the property improvements (dwelling and related structures/equipment essential to the value of the property and subject to flood damage) are located on a site that is within a Special Flood Hazard Area, as designated on maps of the Federal Emergency Management Agency. If so, the DE mortgagee, before submitting the application for insurance to HUD, or the LI mortgagee, before submitting all the required data regarding the mortgage to HUD, must obtain:

(*1*) A final Letter of Map Amendment (LOMA);

(*2*) A final Letter of Map Revision (LOMR); or

(*3*) A signed Elevation Certificate documenting that the lowest floor (including basements and other permanent enclosures) of the property improvements is at least two feet above the base flood elevation as determined by FEMA's best available information (or documenting that the lowest floor meets HUD's elevation standard for newly erected manufactured housing in 24 CFR 203.43f or 24 CFR part 3285, as applicable).

(B) Under the DE program, these mortgages are not eligible for insurance unless the DE mortgagee submits the LOMA, LOMR, or Elevation Certificate to HUD with the mortgagee's request for endorsement.

* * * * *

Dated: March 20, 2024.

Marcia L. Fudge,

Secretary.

[FR Doc. 2024–06246 Filed 4–22–24; 8:45 am]

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Part IV

Department of the Interior

Bureau of Land Management

43 CFR Parts 3000, 3100, 3110, et al.
Fluid Mineral Leases and Leasing Process; Final Rule

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3000, 3100, 3110, 3120, 3130, 3140, 3150, 3160, 3170, and 3180

[BLM_HQ_FRN_MO4500176829]

RIN 1004–AE80

Fluid Mineral Leases and Leasing Process

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is revising its oil and gas leasing regulations. Among other changes, the final rule implements provisions of the Inflation Reduction Act (IRA) pertaining to royalty rates, rentals, and minimum bids; updates the bonding requirements for leasing, development, and production; and revises some operating requirements. The final rule will improve the BLM's leasing process by ensuring proper stewardship of public lands and resources.

DATES: The final rule is effective on June 22, 2024.

FOR FURTHER INFORMATION CONTACT: Yvette M. Fields, Division Chief, Fluid Minerals Division, telephone: 240–712–8358, email: *yfields@blm.gov,* or by mail 1849 C St. NW, Washington, DC 20240, for information regarding the substance of this final rule.

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. For a summary of the final rule, please see the final rule summary document in docket BLM–2023–0005 on *www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

List of Acronyms

APD = Application for Permit to Drill
BLM = Bureau of Land Management
BOEM = Bureau of Ocean Energy Management
CA = Communitization Agreement
CD = Certificate of Deposit
CFR = Code of Federal Regulations
DOI = Department of the Interior
E.O. = Executive Order
EOI = Expression of Interest
FLPMA = Federal Land Policy and Management Act
GAO = Government Accountability Office
GHG = Greenhouse Gas
IBLA = Interior Board of Land Appeals
IIJA = Infrastructure Investment and Jobs Act of 2021
IM = Instruction Memoranda
IRA = Inflation Reduction Act of 2022
LOC = Letter of Credit
MLA = Mineral Leasing Act of 1920, as amended (MLA is also referred to as ''Act'' in the regulations.)
MLAAL = Mineral Leasing Act for Acquired Lands of 1947, as amended
MLRS = Mineral and Land Records System
NAICS = North American Industry Classification System
NEPA = National Environmental Policy Act
OIG = Office of the Inspector General
ONRR = Office of Natural Resources Revenue
PRA = Paperwork Reduction Act
RIA = Regulatory Impact Analysis
RMP = Resource management plan
ROW = Right-of-way
SBA = Small Business Administration
U.S.C. = United States Code

Executive Summary

On July 24, 2023, the BLM published a proposed rule to amend the regulations in 43 CFR parts 3000, 3100, 3110, 3120, 3130, 3140, 3150, 3160, 3170, and 3180 in the **Federal Register** (88 FR 47562), with a 60-day comment period. Generally, the comments supported this rulemaking and expressed the view that the changes outlined by the proposed rule will be helpful. Comments on specific sections of the proposed rulemaking opposed certain provisions and recommended changes. Within this preamble, the BLM discusses those comments and the BLM's responses.

Overall, this rule will enhance the BLM's administration of oil and gas-related activities on America's public lands and reflects Congress's changes to the oil and gas program in the IRA. Specifically, the rule will reflect requirements of the IRA by increasing royalty rates, rentals, and minimum bids for BLM-issued oil and gas leases, and by imposing a fee for the submittal of an expression of interest (EOI) for leasing Federal oil and gas. The rule also updates the bonding requirements for leasing, development, and production to address shortcomings identified in reports by the Government Accountability Office (GAO) and the Department of the Interior's (DOI's) Office of Inspector General (OIG). Collectively, the BLM proposed these changes to bring the regulations into compliance with the IRA and the Infrastructure Investment and Jobs Act (IIJA) mandates and to ensure that reclamation costs are not borne by the American public. The BLM is also adjusting its cost recovery mechanisms so that project applicants provide a more appropriate share of the BLM's up-front costs for processing these applications. Finally, the BLM is implementing several changes to focus leasing on areas with fewer resource conflicts. The BLM's final rule will be the first comprehensive update to the Federal onshore oil and gas program's regulatory framework since 1988.

The Secretary of the Interior manages the Federal onshore oil and gas program pursuant to the requirements of various statutes, including the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1701 *et seq.*) (FLPMA); the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*) (MLA or Act); and the Mineral Leasing Act for Acquired Lands of 1947, as amended (30 U.S.C. 351 *et seq.*) (MLAAL), as well as the recently enacted IRA (Pub. L. 117–169 (2022)) and IIJA (Pub. L. 117–58 (2021)). Under section 102 of FLPMA (43 U.S.C. 1701(a)(7)), the BLM manages approximately 245 million acres of public lands and approximately 700 million acres of federally owned subsurface minerals ''on the basis of multiple use and sustained yield.'' FLPMA's definition of ''multiple use'' in section 103 (43 U.S.C. 1702(c)) requires the BLM to achieve ''a combination of balanced and diverse resource uses that takes into account the long-term needs of future generations for renewable and non-renewable resources.'' Oil and gas-related activities are one of the multiple uses that FLPMA authorizes and which the BLM administers in accordance with the MLA and MLAAL. Both of those Acts govern the leasing of public lands to explore for and develop oil, natural gas, coal, and other hydrocarbons, amongst other mineral deposits.

Discussion of Public Comments on the Proposed Rule

The public comment period for the proposed rule ended on September 22, 2023. During the 60-day public comment period, the BLM received over 215,000 comments submitted by Federal, State, and local governments, local agencies, Tribal organizations, industry representatives, individuals, and other external stakeholders. The vast majority of submissions were form letters. Commenters also submitted roughly 1,000 unique letters. From all submissions, the BLM identified approximately 1,200 unique comments

raising specific issues on the proposed rule.

The BLM carefully reviewed all comments received on the proposed rule. Certain comments suggesting that the BLM address issues outside the scope of this rulemaking are discussed in Section III.A.

The BLM categorized the remaining comments received and provides an overview of those categories and associated responses in Section III.B. The BLM provides more detailed discussions of those comments in Section IV.B. The Federal Government posts all comments at the Federal eRulemaking portal: *http://www.regulations.gov.* To access the comments at that website, enter 1004–AE80 in the Search box and select the Fluid Mineral Leases and Leasing Process proposed rule.

A. Comments Outside the Scope of This Rulemaking

The BLM received many comments directed at matters outside of the scope of this rulemaking, including those regarding: project-specific considerations; the BLM's existing website or computer application programs (*e.g.,* Automated Fluid Mineral Support System, National Fluid Lease Sale System, etc.); additional rulemaking or programmatic environmental impact statements specific to greenhouse gas (GHG) emissions; geothermal or helium leasing activities; and additional operational provisions in 43 CFR part 3160 or additional unit provisions in 43 CFR part 3180 that were not part of the proposed rule. Other commenters recommended changes to national energy policies and priorities, such as to halt all oil and gas leasing activities due to climate change, or discussed matters not specific to the BLM's administration of oil and gas leasing. Many comments expressed general statements of support or opposition to the rule. The BLM has not responded to these comments in detail, because these myriad matters were not encompassed in the proposed rule and are best addressed, if at all, through future rulemakings.

A commenter stated that the BLM failed to write this entire rule in a manner that is easily understood without providing any examples to support the assertion. When drafting the proposed and final rules, the BLM reviewed the rule text to identify areas where the regulations could be written more clearly and made changes as necessary.

B. Categorized Public Comments on the Proposed Rule

This section of the preamble summarizes the major categories of public comments that the BLM received in response to the proposed rule, as well as the BLM's responses.

1. Comments Recommending Additional Oil and Gas Rulemaking, or Policy Development

Summary of comments: Multiple commenters recommended that the BLM initiate additional rulemaking efforts or develop additional policy that are beyond the scope of this rulemaking. These recommendations include: (1) a rule to update the BLM's unitization process in part 3180; (2) a rule to update the BLM's permitting process in 43 CFR part 3160; (3) development of ''The Bureau of Land Management's Blueprint for 21st Century Outdoor Recreation''; (4) updated policy related to oil and gas lease suspension; (5) updated policy related to oil and gas unitization; (6) a similar joint rulemaking between the BLM and the Bureau of Indian Affairs; and (7) a bureau-wide review of its standard stipulation lists.

Response: The BLM reviewed these comments and determined that the requested changes are outside the scope of this rulemaking. With respect to the comments recommending the BLM update the unitization portion of the regulations at part 3180, the BLM made changes to the final rule to implement the increased royalty rate mandated by Congress in the IRA but did not propose any changes to the remaining unitization provisions. As the BLM did not propose any changes in the proposed rule, the public was not provided with a chance to comment on any other changes to the regulations governing unitization. As it reviews its current policy in light of this rule's changes, the BLM will determine whether to implement any changes to its approval process for lease suspensions. Although a comment requested that the BLM review and standardize a list of lease stipulations, in addition to the terms and conditions in the BLM's standard form oil and gas lease, the BLM develops lease stipulations as part of its resource management planning process (which includes analysis under NEPA and other statutes), in which the public has opportunities to comment, and those stipulations apply to oil and gas leases issued within each RMP area. Any site-specific concerns can be addressed through the NEPA process for a particular sale or through conditions of approval at the Application for Permit to Drill (APD) stage.

During the comment period, the BLM received comments requesting additional updates to parts 3160 and 3170. As part of its review under Executive Order (E.O.) 14008, issued on January 27, 2021, the Department reviewed the onshore oil and gas leasing program and published the *Report on the Federal Oil and Gas Leasing Program* on November 26, 2021. The *Report on the Federal Oil and Gas Leasing Program* recommended that the BLM should reform its royalty rate, minimum bonus bids, rental rates, and bonding amounts; establish new requirements for bidders; and take steps to discourage nominations of low-potential lands. When the BLM drafted the proposed rule, the BLM considered any critical permitting or operational changes to parts 3160 and 3170 that were needed in response to the Report's recommendation to reduce speculation but did not propose any changes to the remaining provisions. As the BLM did not propose any changes to parts 3160 and 3170, outside of the limited changes in the proposed rule, the public was not provided with a chance to comment on any other changes to the regulations governing permitting or operations.

As noted above in the summary of comments outside the scope of this rulemaking effort, the BLM received a comment requesting the development of a blueprint for outdoor recreation. Such a revision is beyond the scope of this rulemaking as it would involve revising regulations in Title 43 of the CFR, Subchapter H, and those regulations do not pertain to oil and gas leasing and development, which is the focus of this effort. Finally, a joint rulemaking between the BLM and the Bureau of Indian Affairs is outside the scope of this rulemaking effort.

2. Comments on Greenhouse Gas Emissions and Climate Change

Summary of comments: In the proposed rule, the BLM requested comment on whether the preference criteria in § 3120.34 or other portions of the proposed rule should be expanded, or new provisions added, to discuss analysis of GHG emissions and related decision making based on that analysis. The BLM received many comments recommending different approaches, including:

- Not changing the rule to address GHG emissions and climate change on the grounds that the NEPA review process at the project level provides a sufficient review for climate change issues, and that refraining from leasing Federal minerals will not change the demand for oil and gas production;

- Amending the rule to forgo future leasing based upon the need to avoid exceeding the world's pre-industrial global temperature level by 1.5 degree Celsius;
- Setting lease rates based on the Social Cost of Carbon calculated by the U.S. Environmental Protection Agency in November 2022 at a discount rate of 1.5 percent;
- Aligning the oil and gas program with President Biden's climate goals;
- Limiting GHG emissions via emissions monitoring;
- Implementing a three-stage leasing process to prioritize lands for leasing with a final climate screening;
- Creating a carbon budget for the Federal onshore oil and gas program;
- Requiring climate change mitigation, analyzing climate impacts across BLM-managed lands, or implementing a rule to ensure climate protection for all new leasing and permitting decisions;
- Initiating a programmatic environmental impact statement for the onshore oil and gas program to assess the potential GHG impacts;
- Establishing a quantitative climate test tool to evaluate the relative impact and significance of GHG emissions at the project level; and
- Expanding the competitive leasing preference criteria for conformity with State policies on GHG emissions.

Response: Climate change is a global process that is affected by the sum total of GHGs in the Earth's atmosphere. The BLM acknowledges the views and suggestions reflected in these comments and recognizes that GHG emissions from the Federal onshore oil and gas program contributes to climate change. After reviewing the comments received, the BLM did not make any changes to the final rule to address GHG emissions and climate change. In this rule, the BLM implements regulatory modifications required by Congress in the IRA and other revisions that aim to improve the leasing process and ensure proper management of public lands and resources. These reforms are not focused on climate change. For example, the majority of these regulations cover the administration of an oil and gas lease, such as changes to the fixed filing fees, the fiscal terms mandated by Congress, the type of lease the BLM can issue (eliminating noncompetitive leases as mandated by Congress), and the method by which the public requests lands to be considered for leasing (formal nominations vs. expressions of interest). In implementing the MLA's requirement to hold quarterly lease sales when lands are eligible and available, the BLM will continue to use the NEPA review process and guidance issued by the Council on Environmental Quality to evaluate GHG emissions that result from oil and gas leasing and development and its effects on climate change. The BLM understands the commenters' suggestions and may proceed with those suggestions in future rulemakings that more directly address GHG emissions. Further responses to comments related to the preference criteria specifically are addressed in section IV.B.12 of the preamble.

3. Comments Recommending the BLM Stop All Oil and Gas Lease Sales and Permitting

Summary of comments: Multiple commenters recommended that the BLM stop, or phase out, all oil and gas lease sales, the issuance of leases, as well as permitting and development, due to climate change and the GHG emissions from oil and gas development.

Response: Pursuant to the IRA, the BLM is required to conduct lease sales in order to permit wind and solar energy development projects on public lands. The approach suggested by the commenters thus would require the BLM to stop desirable wind and solar development. In implementing the MLA's requirement to hold quarterly lease sales when lands are eligible and available, the BLM will continue to use the NEPA review process to evaluate GHG emissions that result from oil and gas leasing and development and its effects on climate change.

4. Comments on Public Participation

Summary of comments: Tribes, States, and local governments submitted comments requesting that the BLM update the rule to provide additional consultation and outreach to them on oil and gas leasing and development. Some comments encouraged the BLM to coordinate with the relevant State and county agencies when land-use actions are taken or if the BLM is considering leasing lands adjacent to State-owned or managed lands. Other comments requested that the BLM explore opportunities for Tribal cultural site protection and co-stewardship to ensure the BLM fully advances opportunities for the incorporation of Indigenous Knowledge, respect for Tribal sovereignty and treaty rights, and the protection of Tribal cultural sites. Comments also recommended that the BLM consult the State or local government's land use plans to ensure the BLM applies the appropriate provisions to responsibly manage natural resources, climate, and environmental quality issues during the decision making and planning efforts for oil and gas leasing.

Response: The BLM will continue to engage with the public, Tribes, Federal, State, and local government partners on the BLM's management of its public lands, as appropriate. Subsequent actions that the BLM may take will be subject to the applicable policies, laws, and regulations pertaining to that action, including those for consultation and environmental review. The BLM added language into the competitive leasing process (see § 3120.42) to include scoping, comment, and protest periods to ensure that the BLM provides adequate time to evaluate the views of a wide range of partners, stakeholders, and landowners in any future decisions. Furthermore, in formulating or amending its resource management plans (RMPs), the BLM complies with FLPMA, NEPA, and its regulations providing for public participation, coordination of planning efforts, and consistency. See 43 CFR 1610.2, 1610.3–1, 1610.3–2. The RMPs serve as blueprints to enable the BLM to sustain the health, diversity, and productivity of public lands for the use and enjoyment of present and future generations. Under an RMP, the BLM will identify the lands closed to leasing of Federal oil and gas, the lands open to leasing of Federal oil and gas, and the appropriate stipulations to apply to a Federal oil and gas lease based upon the location of the lease. These decisions are not made as part of this rulemaking and will continue to be made through the BLM's land use planning process, which involves cooperating with State and local governments, consulting with Tribes, and robust public engagement.

The BLM takes its responsibilities to Tribes seriously and respects Tribal sovereignty and treaty rights. Where there are such opportunities, the BLM is committed to exploring co-stewardship opportunities with Tribes. However, co-stewardship is outside the scope of this rulemaking.

5. Comments on the BLM's Discretion To Offer Parcels for Lease Sales

Summary of comments: Multiple commenters stated that the rule improperly limits and discourages exploration or closes off lands to leasing outside of the NEPA process. These commenters pointed to different aspects of the rule to support their claim that the rule limits and discourages exploration. Some comments stated that the rule violates, or evades, the multiple-use mandate of FLPMA or exceeds the authority of the BLM under the MLA. Other comments stated that when a person requests the BLM

include certain lands in an upcoming competitive oil and gas lease sale (via EOI) the BLM should offer all lands described in the EOI in the next available sale based on and consistent with the management decisions made in the relevant RMPs. Multiple comments stated that the new preference criteria (see § 3120.32) will create uncertainty, conflicts among stakeholders and uses, and will hinder the BLM's ability to achieve the congressional mandates such as offering enough acreage for oil and gas leasing in order to allow wind and solar right-of-way (ROW) permit issuance.

Response: With respect to contentions that the BLM's proposed regulations exceed the Secretary's authority to select lands for leasing, the BLM notes that the MLA, 30 U.S.C. 226(a), by providing that the Secretary ''may'' lease lands, necessarily provides the BLM with broad discretion in determining precisely which lands and parcels the BLM will offer at an oil and gas lease sale. Accordingly, the agency has, since at least 1988, consistently applied a public interest determination to any such decisions. *See* 53 FR 22828 (June 17, 1988) (''It is Bureau policy prior to offering the lands to determine whether leasing will be in the public interest.''). The MLA does not specify how and when this decision is to be made, and both the Supreme Court and the U.S. Court of Appeals for the Tenth Circuit have recognized the Secretary's discretion in this sphere. *See Udall* v. *Tallman,* 380 U.S. 1, 4 (1965); *W. Energy All.* v. *Salazar,* 709 F.3d 1040, 1044 (10th Cir. 2013).

Comments asserting that the application of the preference criteria will result in the closure of any lands to oil and gas leasing are incorrect. The BLM has and will continue to make land use decisions at the land use planning stage and document those decisions in the applicable RMP. The preference criteria, on the other hand, were proposed consistent with the MLA to direct the BLM's administrative resources to leasing tracts most likely to be developed, to reduce conflicts between oil and gas development and other public land uses that were not resolved in the resource management plans, and to ''take[ ] into account the long-term needs of future generations for renewable and nonrenewable resources,'' 43 U.S.C. 1702. These criteria may be considered on a case-by-case basis in light of specific circumstances. Even if the BLM were to apply such criteria and decide to defer including particular lands from any particular lease sale, nothing in this rule prevents those lands from being offered in future sales. The RMPs do not always resolve all conflicts, especially those that may be unforeseen or arise due to a change in circumstances. In many cases, this calls for a more specific site review, and the MLA provides the necessary discretion, apart from FLPMA, to engage in this type of site-specific review.

6. Comments Recommending BLM Processes Should Be Addressed in Policy and Not Regulations

Summary of comments: The BLM received multiple comments stating that many of the BLM processes in the proposed rule should instead be expressed in policy documents and that the rule goes beyond the authority of the BLM under the IRA and IIJA. Comments expressed the view that the function of regulations is to inform and instruct the public with regard to actions that they may or may not take while policy interprets those regulations and provides guidance to the agency in implementing them. The commenters stated that inserting existing policy guidance, which applies only to the BLM's actions, into the regulations, rather than leaving it in Instruction Memoranda (IM), is inappropriate. For example, commenters suggested that the preference criteria and the details regarding lease suspensions belong in BLM guidance documents and not in the regulations as these do not impose any requirements on the oil and gas industry. Finally, the commenters stated that the BLM does not need to update the existing regulations governing the BLM's discretionary functions under the existing regulations, since those regulations are adequate to protect the fiscal interests of the American public. These commenters recommended that the BLM only make the changes required by the IRA.

Response: By incorporating provisions such as the preference criteria and lease suspensions into the regulations, the BLM makes those provisions legally binding and provides greater certainty and transparency to the public on the decision-making processes the BLM will use when it processes EOIs (see § 3120.32) and the timeframes for lease suspensions (see § 3165.1). These regulatory criteria may influence a person's decision-making when deciding whether they will submit an EOI or may influence lessees when they are deciding whether to seek a lease suspension. Therefore, the BLM declines to make any changes to the final rule based upon concerns that the changes could be characterized as guidance.

7. Comments on Environmental Justice

Summary of comments: Multiple commenters stated that the BLM should ensure that the final rule includes environmental and social justice considerations as part of the oil and gas leasing process. Comments stated that many of the fluid mineral resources are located in underserved rural areas and on Tribal lands where the fluid mineral industry has a large economic impact. These comments alleged that the rule could undercut environmental justice goals by reducing the economic benefits that would otherwise flow to disadvantaged communities as a result of onshore Federal oil and gas activities. One comment stated that jobs in extractive industries, such as oil and gas development, are not going to the members of the communities burdened by the fossil fuel industry and therefore that the BLM should end the Federal fossil fuel leasing program. Another comment stated that the BLM should solicit the knowledge and experience of those in underserved communities and ensure that these communities' perspectives are meaningfully incorporated into and actively shape planning and decision-making, and the BLM should take into account community-driven and localized health impact assessments and relevant local health and demographic data as part of this process. Another comment recommended that the BLM incorporate environmental justice as part of § 3120.32.

Response: The BLM reviewed the comments recommending changes to the rule to address environmental justice concerns and determined that no changes were necessary. The BLM believes environmental justice concerns are initially addressed through the land use planning process when the BLM is evaluating whether lands should be open to leasing and what stipulations should be imposed, and then at the more site-specific level when identified parcels are being evaluated for possible inclusion in a lease sale. Both of these processes also involve an evaluation under NEPA, which provides an opportunity for considering environmental justice concerns, which are dependent on the specific conditions and history pertaining to each area and the communities potentially impacted. In addition, the preference criteria that the BLM is including in this final rule will provide a tool for the BLM to assess environmental justice concerns through government-to-government consultation and through scoping comments received from the public. To the extent a

comment noted a specific environmental-justice-related concern with a particular section of the rule, the BLM has also addressed such comments in the following Section-by-Section Discussion.

8. Comments on the Impact of the Rule on Indian Leases

Summary of comments: The BLM received a comment stating that the proposed rule preamble incorrectly stated that the rule ''will not impact the leasing of Indian minerals.'' The comment asserted that the rule would impact Indian interest, lands, and minerals, and that the BLM needs to clarify this in the final rule. The BLM also received comments stating that the rule should be revised to clarify that public lands managed by the BLM under FLPMA and do not include Indian lands; that the rule should eliminate BLM activities on Indian lands; and, that the BLM lacks authority to manage activities on Indian lands.

Response: The BLM does not make leasing decisions for Indian lands. However, the BLM does make recommendations for oil and gas operations that may impact Indian lands. Existing regulations at 43 CFR part 3100 outline the BLM's authority over offering lands to lease under the BLM's jurisdiction, which does not include Indian lands. The changes made in this rulemaking clearly fall within the BLM's existing statutory authorities. The BLM acknowledges that some of the proposed changes may affect Indian lands when the BLM makes recommendations for oil and gas operations to the Bureau of Indian Affairs under the Standard Operating Procedures between agencies for the leases they manage under their respective jurisdictions. While the majority of the changes in the final rule impact the leasing of Federal minerals and not Indian leases, there are some provisions that will apply to Indian leases: the operational changes for shut-in and temporarily abandoned wells at § 3162.3–4 and the changes to the APD timeframe at § 3171.14. The BLM has also increased filing fees to account for inflation for applications such as APDs, as required by 30 U.S.C. 191. The BLM considers these updates critical for both Federal and Indian minerals because these changes will give the BLM the ability to complete operator-diligence reviews, ensure that wells are producing on Indian leases as required by law, and to recover its costs to process applications.

9. Comments on the Rule Potentially Discouraging Federal Exploration and Development

Summary of comments: Multiple commenters expressed concerns that the proposed rule would discourage or eliminate future oil and gas exploration and development on Federal lands or would force production from Federal lands onto State or private lands. The BLM also received comments asserting that the combination of proposed § 3120.32 (reflecting the BLM's authority to defer certain parcels) and the increased fees, royalties, and bonding would result in the BLM violating its statutory requirements to prevent waste of the oil and gas resource. Specifically, the commenter claimed that provisions in this rule, such as the competitive leasing preference criteria at § 3120.32, could result in delays in or the complete exclusion of the development of non-Federal minerals in addition to the loss in Federal bonuses and royalties. These commenters also asserted that this rule fails to recognize studies indicating that the United States will continue to need fossil fuels for the foreseeable future. The commenters urged the BLM to look for ways to increase energy development. Commenters also stated that the proposed rule ignored the economic benefit provided by oil and gas development to local schools, hospitals, and infrastructure.

Response: The GAO and the DOI OIG reviewed and audited the BLM's Federal onshore oil and gas program to identify problematic areas in this program and recommended actions to address them. Both the GAO's and OIG's audits [1] highlighted weaknesses in the onshore program's fiscal framework and recommended that the BLM take steps to ensure that the American public receives a fair return from oil and gas activities on public lands. The DOI and the BLM concurred with these recommendations in the *Report on the Federal Oil and Gas Leasing Program* [2] issued in November 2021.

Accordingly, the BLM is adjusting its oil and gas bonding requirements, including by increasing minimum bond amounts for the first time in decades. The BLM is proposing to adjust its cost recovery mechanisms to account for changes in the leasing process since the fees were initially set in 2005. The BLM drafted the proposed rule to: (1) reflect the requirements of the IRA; and (2) enhance the administration of the onshore program, to direct leasing to lands with a higher development potential, and in response to the GAO's and OIG's numerous reports identifying shortcomings in the program, as discussed in the November 2021 *Report on the Federal Oil and Gas Leasing Program.*

The BLM did not make any changes to the final rule based upon the comments expressing concerns that the increased bonding and fees could result in the potential movement of production from Federal to State or private lands. The royalty rates on State and private lands are often higher than those for Federal lands as are the rental rates.[3] Given this, the BLM does not believe the increased rates will have the asserted affect and instead will bring the rates more in line with one another across jurisdictions. Moreover, § 3120.32 does not affect longstanding BLM policies that prioritize leasing parcels subject to drainage (from adjacent State and private minerals); the BLM will continue to work towards leasing lands that will allow for logical development of the minerals by giving preference to lands after accounting for expected yields of oil and gas, fair return for U.S. taxpayers, and decisions embodied by the BLM's RMPs. This will provide for continued development of Federal, State, and private minerals.

IV. Overview of Modifications to the Proposed Rule

A. Summary of Notable Changes

The BLM made changes to the rule in response to comments and for accuracy, clarity, or grammar.

The BLM received numerous comments on the proposed changes to the bonding regulations under subpart 3104, and in response to these comments, the BLM reinstated an operators' ability to post personal bonds secured with letters of credit (LOCs) and

[1] *See, e.g.,* OIG, ''Inspector General's Statement Summarizing the Major Management and Performance Challenges Facing the U.S. Department of the Interior'' (Nov. 2022); GAO, ''OIL AND GAS LEASING—BLM Should Update Its Guidance and Review Its Fees'' (Nov. 2021); GAO, ''OIL AND GAS—Onshore Competitive and Noncompetitive Lease Revenues'' (Nov. 2020); GAO, ''FEDERAL ENERGY DEVELOPMENT—Challenges to Ensuring a Fair Return for Federal Energy Resources'' (Sept. 2019); GAO, ''OIL AND GAS—Bureau of Land Management Should Address Risk from Insufficient Bonds to Reclaim Wells'' (Sept. 2019); GAO, ''OIL AND GAS LEASE MANAGEMENT—BLM Could Improve Oversight of Lease Suspensions with Better Data and Monitoring Procedures'' (June 2018); OIG, ''Bureau of Land Management's Idle Well Program'' (Jan. 2018).

[2] DOI, ''Report on the Federal Oil and Gas Leasing Program'' (Nov. 2021). *https://www.doi.gov/sites/doi.gov/files/report-on-the-federal-oil-and-gas-leasing-program-doi-eo-14008.pdf.*

[3] DOI, ''Report on the Federal Oil and Gas Leasing Program'' (Nov. 2021).

certificates of deposit (CDs). The proposed rule requested comments on if and how the BLM should adjust the minimum bond amounts in the future. After review of the comments, bond amounts will be adjusted for inflation every 10 years so that the minimum bond amounts do not become outdated as they have in the past.

The BLM deleted the existing and proposed sections governing the formal lease nomination process under part 3120.

The BLM revised the final rule to clarify that it will consider the preference criteria in § 3120.32 as part of the scoping process and will apply the criteria after the conclusion of scoping but before issuing the draft NEPA document for the lease sale, consistent with the BLM's existing policy and implementation of IM 2023–007, *Evaluating Competitive Oil and Gas Lease Sale Parcels for Future Lease Sales.*[4]

The BLM also revised the final rule to extend an approved APD's term based on a lease suspension.

These revisions are discussed in more detail in the Section-by-Section Discussion.

B. Section-by-Section Discussion

Sections that did not receive any comments, or that only received comments in support of the proposed changes, are not discussed in this Section-by-Section analysis and are adopted in the final rule as proposed. In addition, throughout the final rule, the BLM replaced the words ''he,'' ''she,'' or ''he/she'' with the appropriate title or entity to comply with Executive Order 13988, *Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation.*

1. Section-by-Section Discussion for Changes to 43 CFR Part 3000

Section 3000.5 Definitions

The BLM received a number of comments on the definition of the terms ''Acreage for which expressions of interest have been submitted,'' ''Person,'' and ''Surface Management Agency.''

With respect to the phrase ''Acreage for which expressions of interest have been submitted,'' a comment stated the BLM should change the definition to ''acreage that is identified in an EOI on land eligible and available for leasing'' to ensure that the BLM accurately determines which EOIs have been properly submitted. No further changes are made to the final rule as the definition already states, ''and for which the BLM may lawfully issue an oil and gas lease.''

Comments on the term ''Person'' recommended that the BLM use the definition in the Federal Oil and Gas Royalty Management Act, 30 U.S.C. 1702, to avoid any unnecessary confusion. The BLM adopts this recommendation and has revised the definition of the term ''person'' in the final rule accordingly.

Comments on the term ''surface management agency'' focused on the assertion that the definition improperly required the BLM to obtain consent from other agencies within the DOI in order to lease lands managed by those agencies, and therefore, that the BLM should not adopt the proposed changes to this definition. Based on these comments, the BLM made additional changes to § 3101.51 to provide that public domain and acquired lands that are open to the operation of the Mineral Leasing Act will be leased only with the consent of the surface managing agency, which, upon receipt of a description of the lands from the authorized officer, can report to the authorized officer that it consents to leasing with stipulations, if any, or withholds consent or objects to leasing.

Section 3000.40 Appeals

The existing § 3000.4 details the appeal rights and exceptions for parts 3000 through 3930. The BLM received suggestions that this section be amended to include State Director Reviews, with an option to further appeal to the Interior Board of Land Appeals (IBLA). The commenters asserted that, without the intermediary appeal to the State Director, there would effectively be no opportunity to appeal in light of average times for IBLA decisions. The BLM does not believe any change to this section is needed. Decisions that are signed at the state office level, which are usually decisions that affect the administration of a lease under parts 3100 and 3120, are signed on behalf of the State Director, meaning that State Director review is not applicable. In addition, 43 CFR subpart 3165 already states that onshore oil and gas operational decisions made under the authority of part 3160 are subject to the State Director Review process and any decision of the State Director is appealable to the IBLA.

Section 3000.41 Severability

This is a new section that the BLM has added in response to comments. The BLM received comments suggesting that it should include a severability clause in the final rule similar to that found in the BLM's realty regulations (43 CFR 2801.8). The final rulemaking adopts this recommendation by adding a new section addressing severability. This section will read, ''If a court holds any provisions of the regulations in parts 3000 through 3180 or their applicability to any person or circumstances invalid, the remainder of these rules and their applicability to other people or circumstances will not be affected.'' The BLM published the proposed rule, in large part, to address the changes required by the IRA, various reports by the GAO and OIG, and the Department's report in response to section 208 of E.O. 14008. Those sections implementing the IRA can and do function separately from those sections proposing new bonding amounts or the competitive leasing preference criteria.

One commenter stated that the courts will determine if a provision is or is not severable from the rule. The comment is correct in that a court will ultimately determine whether portions of the rule can be severed from others in the event a court determines a provision was improperly promulgated. This section is designed to aid that review by demonstrating that the BLM intends the various components of the rule, with various provenances and independent functions, to continue to operate even if one or more of the provisions is declared unlawful.

Section 3000.50 Limitations on Time To Institute Suit To Challenge a Decision of the Secretary

The existing § 3000.5 reiterates the 90-day statute of limitations for judicial challenges to certain BLM decisions under the MLA. The BLM received comments on this section suggesting that the BLM clarify that the regulation does not apply to claims brought under statutes other than the MLA. The final rule does not adopt this recommendation, as this section also applies to other minerals management programs, such as mining claims, which are managed under the general mining laws (see part 3800).

Section 3000.60 Filing of Documents

The existing § 3000.6 specifies where and when documents filed under these regulations must be submitted and provides for filing by electronic means in addition to the hard copy or delivery service, as was previously authorized. Commenters generally supported the proposed changes to this section. Commenters suggested revising the provision to include a requirement that each BLM office designate an email address for filing, and that an e-filing should be deemed timely if it is

[4] *https://www.blm.gov/policy/im-2023-007.*

received by 11:59 p.m. local time in the appropriate BLM office. These changes were recommended to ensure that the appropriate official receives the e-filing and to avoid any risk of default as a result of e-filing with the wrong person in a BLM office. The BLM does not support the use of emails for electronic filings for many of the same reasons stated in the comment, *i.e.,* the potential to be directed to the wrong person and/or wrong office. In addition, the BLM will not incorporate the recommendation to state a specific local time, since the time by which a filing needs to be made is already addressed in 43 CFR 1821.11. The regulation at 43 CFR 1821.11 is entitled, ''During what hours may I file an application?'' and specifically states, ''You may file applications or other documents or inspect official records during BLM office hours. Each BLM office will prominently display a notice of the hours during which that particular office will be open. Except for offices which are open periodically, for example, every Wednesday or the 3rd Wednesday of the month, all offices will be open Monday through Friday, excluding Federal holidays, at least from 9 a.m. to 3 p.m., local time.'' Those instructions necessarily depend upon and encompass the local time at particular BLM offices.

Section 3000.100 Fees in General

The existing § 3000.10 provides general information on the types of fees the BLM may assess, how the fees are calculated, when the fees must be paid and how and when the BLM will adjust any fees. The BLM received a comment recommending a change to paragraph (c), which addresses adjustment of fees, recommending that any adjustments to fixed fees be subject to notice and comment. The BLM declines to make this change as further explained in the discussion of § 3000.120 below.

Section 3000.120 Fee Schedule for Fixed Fees

The existing § 3000.12 lists the fixed fees that must be paid for each transaction requiring a fixed fee and includes transactions that previously did not require a fee, such as the designation of a successor operator; unit agreement applications; subsurface storage agreement applications; unit agreement expansion applications; and formal lease nominations. The final rule removes the formal lease nominations process, consistent with the changes made under § 3120. The BLM received several comments on this section. Some comments supported the BLM's proposal to incorporate processing fees for new actions that were not previously subject to a fee, stating that the fees were appropriate given the BLM's limited resources, or stating that the proposed fees were not sufficient to cover the BLM's costs. Other comments opposed the increased fees, asserting they were excessive, disproportionate, unwarranted, and designed to be a deterrent to Federal oil and gas leasing activities. In addition, some commenters stated that the analysis in the preamble to the proposed rule failed to comprehensively analyze the BLM's fee system, and, specifically, failed to compare the fees to the increased bonus bids, rentals, and bonding. Another comment objected to the application of the new filing fees, royalty, and rental provisions to leases sold before the enactment of the IRA but issued after the IRA.

The preamble to the proposed rule outlined the processing steps considered by the BLM in calculating each of the fees. The general comments only criticized the processing steps associated with the BLM's review of a competitive lease application fee, as discussed below. No comments criticized the processing steps for the other application fees; therefore, the BLM will implement the proposed fixed filing fees as stated in the preamble to reimburse the BLM for its processing costs. With respect to the fixed filing fees, the preamble specifically stated that the BLM would not charge a new fixed filing fee under this rule for processing a document that the BLM received before the effective date of the rule. Documents submitted before the effective date of the final rule will be processed based on the fee that was in effect when the document was submitted.

One comment recommended that the competitive lease application fee, which includes the cost for the BLM to undertake any necessary NEPA review, should not be a fixed fee and instead should be determined on a case-by-case basis under § 3000.110, or, alternatively, that the cost should be fixed but that the applicant should have the option to request a case-by-case fee determination to establish a fee for a particular lease application. Although the BLM understands the impetus for suggesting that the fee be determined for a particular lease, the BLM cannot adopt the proposed change, because the NEPA analysis prepared for each lease sale covers all of the parcels offered in a given sale and is not for each individual parcel. Moreover, the competitive lease application fee is collected after the NEPA review has been completed, and after the lease sale has been held. Therefore, the applicant would not be able to help pay for the preparation of any BLM NEPA document before performing any case processing on a parcel-by-parcel basis.

Other comments stated that the BLM should charge fixed filing fees for compensatory royalty agreements and communitization agreements (CAs). The final rule includes a fixed fee for compensatory royalty agreements under ROW pursuant to subpart 3109 where the processing steps are the same for leases. The BLM added the following clarifying language to this provision in the final rule: ''Leasing and compensatory royalty agreements applications under right-of-way pursuant to subpart 3109.'' The BLM does not adopt the recommendation to require a fixed filing fee for CAs. The BLM explained in the preamble to the proposed rule that new fixed filing fees were considered for Federal CAs (§ 3105), Federal participating area applications (§ 3180), and royalty rate reduction applications (§ 3103), but it ultimately declined to propose these fees due to the low value and the public benefit related to these items.

The BLM received suggestions that the Bureau clarify requirements for the fixed filing fee for designation of successor operator for Federal agreements, such that the fee would not be required when a successor operator is designated for contracted unit agreements that do not contain Federal lands. The BLM adopts the suggestion and has revised the Processing and Filing Fee table in this section of the final rule to include the following language: ''Designation of successor operator for all Federal agreements, except for contracted unit agreements that contain no Federal lands.''

The BLM also received several comments stating the BLM erred in adding the fee for EOIs to the fixed filing fee table, because these fees are adjusted for inflation every year; and section 50262(d) of the IRA expressly authorizes the Secretary to only adjust the EOI fee ''not less frequently than every 4 years . . . to reflect the changes in inflation.'' The BLM concurs with this comment and has moved the EOI fee to the new § 3103.1(a) where it will be adjusted based on inflation every 4 years.

Another comment stated that the BLM did not explain its authority to impose an annual inflation adjustment and that for the annual inflation adjustment, the BLM must re-apply all of the factors set out in section 304(b) of FLPMA, make a new determination as to whether the fee warrants an adjustment, and similarly codify the determination via

rulemaking every time a fee is adjusted. A similar comment asked the BLM to consider the disproportionate impact continued increases have on the total cost to develop Federal minerals.

Section 304 of FLPMA, 43 U.S.C. 1734, authorizes the BLM to establish fees intended to reimburse the government for reasonable costs and authorizes the Secretary to change or abolish such fees. The BLM establishes fees based upon the reasonableness factors at section 304(b) of FLPMA, which include ''actual costs (exclusive of management overhead), the monetary value of the rights or privileges sought by the applicant, the efficiency to the government processing involved, that portion of the cost incurred for the benefit of the general public interest rather than for the exclusive benefit of the applicant, the public service provided, and other factors relevant to determining the reasonableness of the costs.'' Once the BLM establishes a fee, the BLM adjusts the fees for inflation annually to effectively keep fees in line with current costs. This process comports with the broad authority given to the BLM in section 304 to set reasonable fees. The BLM did not propose changes to this method, or how the fees are adjusted annually for inflation in this proposed rule. The BLM will not use an alternative method for annual fee adjustments as it would require collecting data periodically for each fee, which is inefficient, costly, and impractical. However, as recommended by the GAO,[5] the BLM did review the six factors, commonly known as ''FLPMA reasonableness factors'' in section 304(b), to account for changes in the leasing process since the fees were initially set. For the proposed rule, the BLM: (1) contacted each office with this type of application (the 10 state offices or all of the 40 field/district and state offices depending on the application type); (2) requested the offices to provide the average processing time for each type of application and the employee completing this work; (3) received the estimates from each office; (4) calculated the weighted average for each type of application; (5) reviewed the monetary value of the right or privilege that the applicant seeks; (6) evaluated how efficiently the BLM processes a document based upon the processing times; (7) reviewed the public benefit factor for the application; and (8) reviewed the public service factor for the application. The preamble to the proposed rule reflects this analysis of its fixed filing fees. Without the inflation adjustment that has existed since 2005, the BLM would instead be required to complete the same burdensome, eight step review under FLPMA for every subsequent update.

Furthermore, to verify the accuracy of the BLM's method for determining fees, the BLM reviewed a common oil and gas fixed filing fee—assignments and transfers—which has not experienced changes to the process since 2005. The BLM intentionally selected the assignment and transfer fixed filing fee as the most representative filing fee to review because (1) assignments and transfers are the most common application received by the BLM; (2) the other applications that require filing fees are more rarely used; and 3) all state offices are familiar with the assignment and transfer application. After completing the review of the assignment and transfer fixed filing fee for the proposed rule, the BLM compared the outcome of that review with the inflation adjustments (86 FR 54636 (Oct. 4, 2021)). The review identified that the assignment and transfer fixed filing fee should be $100 in FY2022 based upon the FLPMA factors. This amount matched the inflation-adjusted fixed filing fee for FY2022, which was also $100. Therefore, the FY2022 inflation adjustment matched the calculated fixed filing fee based upon the FLPMA factors in FY2022. If the BLM's review process changes for an application, and thus there is the potential that reasonable costs may change outside of the cost of inflation, the BLM would update the fixed filing fees based upon the FLPMA factors and provide the opportunity for notice and comment.

Finally, the BLM requested comments related to changing its current process, which requires publishing the annual fee adjustments as a final rule in the **Federal Register** and then incorporating the new fees in the Code of Federal Regulations (CFR). Instead, the BLM proposed to post the updated table on the BLM's web page with the historical fees posted in the same location.

Commenters stated that since the fixed filing fees are not subject to appeal, the BLM should remove this provision; that adjustment of the fees should include a notice and comment period; and that the BLM should continue to publish the annual fee adjustments in the **Federal Register**.

The BLM is updating the final rule to state that the BLM will ''announce annually in the **Federal Register**'' revised fees, as well as posting the fees to the website. The BLM initially promulgated the fixed filing fees in 2005 after conducting a notice-and-comment rulemaking. Each year since, the fees have been adjusted for inflation through a final rule without further notice and comment. This is because the BLM included the method used to calculate inflation in its proposal in 2005, and the same method has been used for each subsequent increase. As stated in the proposed rule, the BLM will follow this same procedure for any new fees. For example, the BLM will: (1) publish a proposed rule with information on the proposed fee and propose to adjust the fee based on inflation; (2) review the comments received on the proposed rule for the new fixed filing; (3) publish a final rule with the new fixed filing fee; and (4) adjust the new fixed filing fee based upon inflation without notice and comment for any subsequent increases. This process negates the need for notice and comment every time the BLM adjusts the fee solely for inflation. These periodic inflation adjustments are not subject to appeal.

Additionally, as stated above, if the BLM's review process for any application changes, and thus there is the potential that the BLM's reasonable costs may change outside of the cost of inflation, the BLM would review the FLPMA factors to update the fixed filing fees and provide the opportunity for notice and comment.

The BLM adopts the proposed change to publish the fixed filing fees on the BLM's web page and to publish the adjusted fees each year in the **Federal Register** to provide additional public notice. The table in this section will still contain a list of the types of applications that require a fixed filing fee, but the fee itself will be removed from the table so it does not become outdated as each subsequent adjustment for inflation is made. In addition, the BLM modified the regulatory text to reflect that the table in 3000.120 does not include the actual fee amounts. When fees are added, deleted, or need to be adjusted due to changes in the processing steps for the application or a change to the method to calculate the inflation adjustment amount, the BLM will do so by a notice and comment rulemaking.

Section 3000.130 Fiscal Terms of New Leases

The provisions within § 3000.130 only apply to oil and gas leasing; therefore, the BLM moved the fiscal terms for new leases to a new section under subpart 3103 for Fees, Rentals and Royalty in the final rule in response to comments stating that failure to specify the rental amounts, within the context of the regulation on annual

[5] GAO. GAO–22–103968: OIL AND GAS LEASING BLM Should Update Its Guidance and Review Its Fees. *https://www.gao.gov/assets/gao-22-103968.pdf.*

rentals, would be a disservice, detracting from the regulations' value as an orderly source for basic information.

2. Section-by-Section Discussion for Changes to 43 CFR Subpart 3100

The BLM received a recommendation to reference its legal authority and duties under FLPMA and NEPA in all authority citations in the regulation. The BLM concurred in part and added a full reference to FLPMA into the authority introduction to the regulatory text, which changes ''43 U.S.C. 1732(b), 1733, and 1740'' to now state, ''43 U.S.C. 1701 *et seq.*'' This update was only made to part 3100 since the other authority references already include a reference to FLPMA. The BLM did not add NEPA into the authority section, as NEPA does not provide the BLM with any authority for leasing.

Section 3100.3 Authority

The existing § 3100.0–3 sets out the BLM's authority for leasing on various types of lands, such as public domain land and acquired lands. During the comment review period, the BLM decided to add clarifying language in the final rule on Wild and Scenic Rivers to comply with the Wild and Scenic Rivers Act (16 U.S.C. 1280). Therefore, the final rule makes the following adjustments to the language for the Wild and Scenic Rivers exceptions listed under both Public Domain and Acquired lands: ''subject to valid existing rights,'' is moved to the beginning of the sentence to clarify that this applies to all types of National Wild and Scenic Rivers Systems lands. The following clarifying language is added to the end of the sentence ''lands within designated Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-quarter mile of the bank of certain rivers designated as scenic or recreational, and in some cases, designating legislation may apply a different boundary extent. Lands within the National Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-half mile of the bank of any river designated a wild river by the Alaska National Interest Lands Conservation Act (16 U.S.C. 3148).''

The BLM received a comment on paragraphs (a)(1) and (b)(1), suggesting that the BLM change the phrase ''are subject to lease'' to ''may be subject to lease'' to align with the discretion afforded the Interior Secretary under the MLA, 30 U.S.C. 226(a), that lands ''may be leased.'' The final rule does not adopt this recommendation. In 1920, Congress enacted the MLA to facilitate the exploration and development of oil and gas and other federally owned minerals. The MLA specifies the lands that are subject to the statute, and then provides discretion to the Secretary to determine which of those lands may be leased. The first step in exercising that discretion is making decisions in the BLM's resource management plans under FLPMA. The BLM declines to change this phrase so as not to confuse this section on the authority to lease, including the exceptions listed under both public domain and acquired lands, where there is no discretion to lease ineligible lands.

A comment recommended that paragraphs (a)(2) and (b)(2) rely solely on the subhead—Exceptions—to indicate what the provisions in the sections mean and, for clarity, that the BLM should consider inserting language to the effect of: ''The following lands are not subject to lease.'' The final rule adopts this recommendation.

The BLM received a comment requesting that the BLM identify additional exceptions for both public domain and acquired lands. This exception would specify that the BLM cannot lease lands identified in the land use plans as unavailable for oil and gas leasing or otherwise determined by the authorized officer to be inappropriate for leasing to protect other multiple use resources and values. The final rule does not adopt this recommendation. As stated in the proposed rule, the purpose of this section is to describe lands subject to leasing, and changes proposed to this section were made to provide clarity and to conform the regulations to exceptions identified in various other laws. The change requested by the comment does not meet this requirement, as the comment addresses discretionary decisions regarding leasing. Moreover, the concerns represented by this comment are already addressed in the BLM's land use planning process, NEPA reviews, and other processes that identify suitable areas for leasing.

Section 3100.5 Definitions

The existing § 3100.0–5 sets out the definitions applicable to part 3100. The BLM added new proposed definitions for ''competitive auction,'' ''exception,'' ''modification,'' ''oil and gas agreement,'' ''qualified bidder,'' ''qualified lessee,'' ''responsible bidder,'' ''responsible lessee,'' and ''waiver.'' The BLM received several comments on this section requesting additional definitions for ''bad actors,'' ''current land use plan,'' ''exclusion area,'' ''mitigation,'' ''permanent impairment,'' and ''preferred leasing area.'' Since these terms are not used in parts 3000, 3100, and 3120, the BLM has not adopted these recommendations.

In addition, a comment recommended adding a definition for ''restoration.'' The BLM declines to make this change given that § 3104.10, where this term is used, specifically states that the restoration is to be ''in accordance with, but not limited to, the standards and requirements set forth in 43 CFR 3162.3 and 3162.5 and orders issued by the authorized officer.'' This flexible definition does not warrant modification at this time.

Some comments recommended that the BLM expand the definitions in this section to include the terms ''eligible'' and ''available.'' The BLM declines to define those terms by regulation at this time and may revisit the issue in future rulemakings.

One commenter requested that the BLM remove the definition for ''modification'' to avoid confusion where this term is used in contexts other than changes to lease stipulations. The BLM agrees there is a potential for confusion given the numerous different contexts in which the word ''modification'' is used and has therefore revised the definition to clarify that it only applies to lease stipulations. For similar reasons, the BLM has made changes to ''exception'' and ''waiver'' in the final rule. Each definition now includes the phrase ''as used for lease stipulations.''

A comment recommended modifying the term ''oil and gas agreement'' to reflect the fact that an agreement may in some instances include unleased lands. The BLM adopts this recommendation.

The BLM received a comment suggesting that the term ''operator'' should be revised to explicitly state that the operator holds operating rights and thus has the same obligations as the operating rights owners to plug wells and remediate the well sites. The BLM does not concur with the recommendation, as an operator could be a lessee and may or may not own operating rights. The current definition for ''operator'' states, ''including, but not limited to, the lessee or operating rights owner, who has stated in writing to the authorized officer that it is responsible under the terms and conditions of the lease for the operations conducted on the leased lands or a portion thereof.'' Therefore, the BLM kept the existing definition of ''operator'' in the final rule.

The BLM received several comments on the proposed definitions for the terms ''qualified bidder,'' ''qualified lessee,'' ''responsible bidder,'' and ''responsible lessee.'' Those comments that supported the inclusion of these

new definitions suggested modifications that would also exclude from those terms anyone with a history of failing to make timely rental or royalty payments; failing to meet a diligent development obligation; maintaining a significant number of inactive wells; engaging in repeated or ongoing environmental, worker safety, or labor violations; violating State reclamation requirements on other leases; or engaging in lease speculation, such as failing to drill approved APDs, or holding large quantities of undeveloped leases.

The BLM declines to include this language, which is too vague and overlooks existing enforcement tools. For example, when a company fails to make timely payments, such as rental payments, the Act already dictates that the lease will automatically terminate through operation of law. In addition, if a company fails to make royalty payments after being notified such payments are due and exhausting its legal remedies, the Office of Natural Resources Revenue (ONRR) may refer an entity to the Federal suspension and debarment list. It is the BLM's policy to check SAM.gov (the Federal suspension and debarment site) before issuing a lease or approving an entity to acquire a lease interest through an assignment or transfer of operating rights. The BLM may also take enforcement actions when lessees violate the terms of a lease, including environmental, worker safety, or labor standards. The BLM does not agree that a company's decision to not drill a well or develop leases should determine if they are responsible or qualified, because such fact-specific business decisions do not, by themselves, determine whether a lessee has acted irresponsibly or incompetently. The BLM generally lacks the capacity to investigate and evaluate State law reclamation violations; however, the current definition for responsible lessee provides for the lessee to be in compliance with statutes applicable to oil and gas development. While it is not the BLM's practice to investigate a person's compliance with State law reclamation requirements, the BLM would not ignore a person's noncompliance when it has been brought to the BLM's attention for consideration if a person is a responsible lessee prior to lease issuance.

Other comments suggested that, in connection with these definitions, the BLM should: (1) create a public registry of individuals and companies currently identified as not being responsible bidders and/or lessees, and make the list of ''Entities in Noncompliance with Reclamation Requirements of section 17(g) of the MLA'' public and updated on a regular basis; (2) clarify, in § 3108.30, that leases are subject to cancellation if the lessee is found not to be a ''qualified lessee'' or a ''responsible lessee''; and (3) implement a system that allows States, local government, Tribal governments, and individuals to report behavior or conduct that warrants investigation.

The BLM updates the list of ''Entities in Noncompliance with Reclamation Requirements of section 17(g) of the MLA'' on an as needed basis, and then forwards the names of the entities to the Federal Government's suspension and debarment program. SAM.gov is a publicly available website. In turn, when a company returns to compliance, the BLM notifies the suspension and debarment program that the entity should be removed from SAM.gov. The cancellation provisions in § 3108.30 contains language for entities that fail to comply with the laws and regulations. The BLM also notes that any entity or individual can contact the BLM to report behavior or conduct that warrants investigation, and the BLM declines to create a separate regulatory system for this purpose at this time.

The BLM also received comments regarding the new definitions for ''qualified bidder,'' ''qualified lessee,'' ''responsible bidder,'' and ''responsible lessee.'' One comment suggested that the term ''qualified bidder'' does not take into account that brokers or non-operating partners bid on leases, and that the new term could substantially impede bidding if it were to mandate that bonding or similar bidder requirements that historically only applied to a lessee be in place prior to bidding. The BLM considered the involvement of brokers or non-operating partners when it drafted these definitions, which is evidenced by the separate definitions for ''qualified bidder'' and ''responsible bidder'', as well as to whom the lease is issued (''qualified lessee'' and ''responsible lessee''), since these may not be the same entities. In addition, there is no mandate, in either the proposed or final rules, for bonding or similar requirements prior to bidding.

Another comment suggested that the BLM should clarify in the definitions (and in proposed § 3102.51) that it will continue to adhere only to the factors in MLA section 17(g), 30 U.S.C. 226(g), in determining who may hold a lease. The BLM disagrees. The MLA, 30 U.S.C. 226(b)(1)(A), refers to responsible qualified bidders and specifically states that: ''[a]ll lands to be leased which are not subject to leasing under paragraph (2) shall be leased as provided in this paragraph to the highest responsible qualified bidder by competitive bidding under general regulations in units of not more than 2,560 acres, except in Alaska, where units shall be not more than 5,760 acres.'' The MLA also states that ''[t]he Secretary shall accept the highest bid from a responsible qualified bidder which is equal to or greater than the national minimum acceptable bid, without evaluation of the value of the lands proposed for lease.'' The BLM's regulations reiterate and rely on these statutory terms. Specifically, because a person who bids on a lease is not necessarily the same person to whom the lease is issued, it is appropriate to include definitions for ''qualified bidder'' and ''responsible bidder,'' as well as definitions for whom the lease is issued, *i.e.,* ''qualified lessee'' and ''responsible lessee.''

Another comment on the definitions for ''responsible bidder'' and ''responsible lessee'' questioned the inclusion of the phrase ''history of noncompliance'' with applicable regulations and lease terms, stating that the meaning of a ''history of noncompliance'' is unclear. The comment suggested that the phrase could be construed broadly to mean that, if a person ever was found to have been in noncompliance with the terms of its Federal oil and gas lease or applicable regulations, that person could be precluded from obtaining future Federal lease interests, even if they corrected the alleged noncompliance or disputed the alleged violation and won.

The BLM agrees the term is imprecise and has revised the definitions by changing the phrase ''does not have a history of noncompliance'' to ''is in compliance.'' A lessee would not be precluded from obtaining future Federal lease interests if it corrected the noncompliance. A lessee's noncompliance ends: (1) when the entity has paid all civil penalties and performed the required reclamation; (2) the BLM accepts the required reclamation performed under contract, and the entity reimburses the U.S. for all costs associated with the required reclamation, including the costs associated with the BLM's issuing and overseeing the performance contract during its life; and (3) if the bond is collected and is insufficient to cover the total costs, the entity pays the entire amount due to the U.S. and the BLM accepts compliance. This is outlined in

the BLM handbook H–3120–1, *Competitive Leases,* Appendix 4.[6]

The BLM proposed to separate the definitions for ''assignment'' and ''sublease'' from the current definition of ''transfer'' in the existing regulations. One comment stated that a greater understanding of the differences between assignment and transfer of operating rights is long overdue. Another comment stated that the BLM's definitions for ''assignment'' and ''transfer'' have corresponding, but different, meanings; that the Bureau of Ocean Energy Management (BOEM) recently issued a proposed rule stating that the terms are interchangeable; and that the BLM should ensure consistency and clarity in use of these terms between the two bureaus regulating Federal oil and gas leasing onshore and on the Outer Continental Shelf. The BLM reviewed its definitions and believes the two terms are distinct and should remain separate. An assignment of record title conveys both record title and operating rights and is limited under § 3106.10 to certain restrictions that do not apply to transfers. The BOEM regulations do not have this distinction, which is why the BLM is retaining the separate definitions.

Comments recommended adding a definition for ''unnecessary or undue degradation.'' The BLM declines to define this phrase in this rule because it is used only once, in § 3120.32, and such a definition would benefit from public input before promulgation. As used in § 3120.32, the phrase reflects the ordinary meaning of the terms used in section 302(b) of FLPMA.

Section 3100.22 Drilling and Production or Payment of Compensatory Royalty

The existing § 3100.2–2 addresses drainage protection, an express covenant of the lease agreement. Under the terms of Federal leases, the lessee has the obligation to protect the leased land from drainage by drilling and producing any well that is necessary to protect the lease from drainage, or, in lieu thereof and with the consent of the authorized officer, by paying a compensatory royalty assessment to the Federal government. The BLM did not propose changes to this section but did receive a comment stating that the BLM should consider using this opportunity to amend this section to (1) clarify when drainage involving two Federal leases with different fund distribution codes occurs; and (2) specify that the lessee may resolve drainage by creating a federally approved agreement for sharing production among the affected leases. These proposals already reflect current policy; refer to the BLM Manual Section 3160, *Drainage Protection Manual.*[7] The Drainage Protection Manual provides guidelines, standards, and procedures to prevent the loss of oil and gas resources and any resulting loss of royalty revenues from drainage on leased and unleased public domain, acquired, and Indian lands. The BLM does not believe changes are needed to this section since these proposals are already allowed under the current regulations to address possible solutions to drainage.

Section 3100.40 Public Availability of Information

The proposed rule stated that the BLM was considering adding language that would provide notice that names and addresses of the nominator, lessee, operating rights holders, and operators would be made public on the BLM's Mineral & Land Records System (MLRS). The BLM's lease and agreement case files are already public records, and any change to the existing § 3100.4 would merely reflect the BLM's current practice. The BLM received comments supporting additional changes to this section, stating that it should be made clear to nominators, lessees, operating rights holders, and lessees that their identities will be made public through the MLRS rather than the current practice, which requires a member of the public to be at the BLM state office to submit a paper request to document the case file. The BLM will continue to release the names and addresses of nominators, lessees, operating rights holders, and lessees to the extent allowed by the Privacy Act to ensure there is a transparent onshore leasing process and does not believe any further changes to this section are needed. The names and addresses of individuals were redacted from all reports, including Serial Register Pages, as a result of a recent privacy review. The redacted information only applies to individuals (MLRS personal accounts) and not companies (MLRS business accounts). Specifically, the privacy review determined that all personal accounts regardless of type of case are considered to contain Personally Identifiable Information (PII). In order to release this PII—specifically names and addresses that are collected of our applicants/interest holders—the BLM must meet two requirements. First, the BLM must establish and disclose a routine use for the information—which, in other words, is establishing that the public need and benefit outweighs the need for the protection of the privacy information and notifies that the PII may potentially be released. This has been completed by disclosing the routine uses contained in BLM System of Records Notice (SORN) LLM32 in accordance with the Privacy Act. The SORN LLM32 is for Lands & Minerals Authorization Tracking System and covers the data from both LR2000 and MLRS. Most requests made in the Information Access Center at the state offices fall under routine use number ''(2) to Federal, State, or local agencies or a member of the general public in response to a specific request for pertinent information.'' Second, to meet Privacy Act requirements, the BLM must be able to track who received the information, when, and for what purpose to satisfy the Privacy Act's requirement that the information was released in accordance with a ''specific request for pertinent information.'' A member of the public can create an MLRS account to view unredacted information. This log in method allows for the BLM to meet this requirement through a logging system.

The BLM received a comment stating that the BLM provides no justification for publishing information on all entities registered to bid during a lease sale, rather than providing this information only for issued leases. Publishing participants in oil and gas lease sales has been a long-standing Bureau policy to provide transparency in the competitive leasing process. Refer to H–3120–1 *Competitive Leases* handbook, published February 2013.[8] This policy specifically states, ''Names of bidders/high bidders remain confidential until the end of the sale.'' In addition, each Notice of Competitive Lease Sale provides adequate notice that the names and addresses of bidders will be released and no further changes to the lease sale process are needed.

Another comment stated that the final rule should also authorize researchers to use lease and production data to analyze market-level royalty, bid, and rental rates. The comment then stated that independent, professional analysis would provide the BLM with critical data on the appropriate market-level rates for Federal mineral charges. In addition, the commenter also stated that the final rule should authorize the BLM to provide a quarterly report to the

[6] *https://www.blm.gov/sites/blm.gov/files/uploads/Media_Library_BLM_Policy_h3120.pdf.*

[7] BLM. MS–3160, *Drainage Protection Manual* (Public). *https://www.blm.gov/sites/blm.gov/files/uploads/mediacenter_blmpolicymanual3160.pdf.*

[8] BLM: H–3120–1, *Competitive Leases* handbook. *https://www.blm.gov/sites/blm.gov/files/uploads/Media_Library_BLM_Policy_h3120.pdf.*

public on all revenues received from leasing and mineral production on Federal lands on a lease-by-lease basis, and as the ultimate owners of the lands and minerals being leased, the public has a right to know this information. The BLM makes lease information, including lease terms such as rental rates and royalty rates, available through the MLRS; however, because the amount of royalty is a function of production and proprietary data is confidential, the royalty amount the Federal government receives cannot be released on a lease-by-lease basis. The public may obtain general information on production data, rental, and royalty payments from the ONRR.

Section-by-Section Discussion for Changes to 43 CFR Subpart 3101

Section 3101.12 Surface Use Rights

The proposed rule revised the existing § 3101.1–2, which was originally promulgated in 1988, to provide that the BLM could impose reasonable measures under the lease terms to avoid, minimize, or mitigate adverse impacts to other resource values, land uses or users, federally recognized Tribes, and underserved communities. Those reasonable measures include site-specific minimum siting and timing parameters that the BLM may impose on lessees to protect the public interest.

The BLM received numerous comments on this section, including: (1) support for the proposed changes, and statements that the changes are critical to mitigate impacts when the relevant RMP is outdated; (2) requests for clarification that leases are contingent on NEPA analysis and not a lessee's expectation; (3) requests for clarification that a lessee's surface use rights are subject to a land use plan's term, including terms provided for by land use plans either revised or amended after a lease is issued; and (4) requests for the BLM to clarify that the agency retains its full authority to condition development and production on leases after the lease is issued in order to respond to findings of site-specific NEPA analyses or changing conditions between the time a lease is issued and when it is developed. These changes are unwarranted as the BLM has the authority to impose measures that are more stringent than those in the regulations as long as they constitute reasonable measures to minimize adverse impacts, *Yates Petroleum,* 176 IBLA 144, 156 (2008). Therefore, the BLM is not revising this section further based on these comments, many of which request unwarranted or unnecessary clarification or specificity that would exceed the scope of this rulemaking.

Some comments opposed the proposed changes to this section, including by asserting that: (1) distance/siting requirements could lead to the BLM exceeding its authority to regulate air quality; (2) the BLM did not reference a lease provision that grants the agency the proposed new authority to constrain or deny lease operations; and (3) the BLM should consider public welfare when determining which measures may be reasonable. The BLM has the authority to use terms and conditions under Section 6 of the standard lease form to control site-specific environmental or public welfare impacts on leaseholds, as opposed to using lease-specific protective measures in lease stipulations from the RMPs.[9] Section 6 of the standard lease form authorizes the BLM to require ''reasonable measures'' to the extent that such measures would be consistent with the lessee's lease rights. The existing regulation has been misconstrued as limiting the BLM's authority to establish reasonable measures to protect resources and to establish minimum parameters within which the BLM can specify site-specific mitigating measures that are consistent with the lease rights granted a lessee.

Comments requested (1) the removal of language that arguably suggests that the BLM could require a lessee to ''avoid'' or ''mitigate'' all adverse impacts of developing mineral rights; and (2) that the final rule specify how water sources will be protected. The BLM has revised this section by clarifying that not all surface impacts must be mitigated and by clarifying the distance the BLM may require operations to be moved. The final rule strikes the words ''avoid, minimize, or'' since this is not needed as avoidance and minimization are integral to mitigating adverse impacts.

Some comments requested changes to require the relocation distances to be either a maximum of or be at least 1 mile and requested the BLM to prohibit new surface disturbing operations. The language in this section has been in place since at least 1988 and does not prohibit new surface disturbance. The BLM proposed to change only the minimum siting and timing parameters to account for changes in technology. The BLM declines to further increase or set a maximum parameter as this would not allow the flexibility that may be required to avoid resource conflict. The final rule amends the last sentence of the section to clarify the intent of the proposed rule. The proposed rule removed the phrase ''At a minimum'' from the existing regulations but retained the phrase ''by more than.'' The final rule is amended to state, ''At a minimum, modifications that are consistent with lease rights include, but are not limited to, requiring relocation of proposed operations by up to 800 meters,'', which allows the BLM to require a lessee to relocate proposed operations by up to 800 meters to avoid a resource conflict that may not have been identified at the time the BLM issued the lease. For example, the BLM may need to move operations to avoid a sage grouse lek, a contingency that may not be encompassed by standard lease terms. In that circumstance, this provision would allow the BLM to move the operations up to 800 meters to minimize the impacts to the sage grouse lek. As stated in the 1988 final rule preamble for the existing regulations, ''Similarly, the authority of the BLM to prescribe ''reasonable,'' but more stringent, protection measures is not affected by the final rulemaking,'' see 53 FR 17341 (May 16, 1988). This section does not apply to the protection of resource values that are already addressed in lease stipulations.

Comments requested that the BLM strike the word ''specific'' as a modifier for ''nondiscretionary statutes'' that provide post-lease restrictions on surface use rights. The final rule adopts the recommendation to strike the word ''specific'' as a modifier to nondiscretionary statutes.

Comments stated that the language explicitly allowing a BLM officer to restrict the development of a project to proactively avoid impacts to ''land users'' or ''underserved communities,'' is improper because, the commenter contended, such language is vague and would improperly expand the BLM's authority, potentially encroach upon a lessee's lease rights, and cause uncertainty. Other comments requested that the BLM add ''overburdened and'' before ''underserved communities'' in the final rule, and that the BLM better specify procedures the BLM could use to protect multiple use standards and Native Americans' land rights in areas near reservations. For the reasons explained below, the BLM does not agree with these comments and retains its proposed language to proactively avoid impacts to ''land users'' or ''underserved communities.''

The term ''land users'' is already used in the existing 43 CFR 3101.1–2 and is specifically included in Section 6 of the

[9] Stipulations are additional specific terms and conditions that change the manner in which operations may be conducted on a lease or modify the lease rights granted.

standard lease form. This term identifies segments of the public that use the land for recreation or for economic growth in the community. Like the term, ''resource values''—which the BLM's regulations do not define—the term ''underserved communities'' has a straightforward and commonly understood meaning that would not benefit from elaboration here, and the BLM has an obligation under the MLA and APA to articulate a rational connection between underserved communities and the proposed operations, as modified by the BLM. Based on the above, the BLM declines to modify or remove either ''land users'' or ''underserved communities.''

Section 3101.13 Stipulations and Information Notices

The BLM proposed to split the existing § 3101.13 into two separate provisions and add a new paragraph (a), stating the BLM would consider the sensitivity and importance of a resource when developing stipulations without regard to the restrictiveness of the stipulation.

One comment on this section recommended that the consideration of affected resources and potential uncertainty be made mandatory by substituting ''shall'' or ''must'' for ''may'' in the final rule text to remove any uncertainty. The BLM declines to make this change so as to maintain discretion when considering potential stipulations. The BLM requires this discretion because the BLM need not consider every potentially affected resource for each parcel. Instead, the BLM will use its discretion to determine, based on the sensitivity, importance, and any uncertainty, which resources should be considered, and will then assess whether those resources are adequately protected by stipulation.

Some comments stated that the BLM should delete the proposed paragraph (a) [10], arguing that the language is subjective and would allow the inclusion of new stipulations that were not addressed in the underlying planning documents. Some comments stated that proposed paragraph (a), and in particular the phrase ''without regard to the restrictiveness of the stipulation,'' disregards the principle of multiple use by elevating certain uses or allows the BLM to essentially prevent oil and gas operations. Another comment recommended changing the phrase ''without regard'' to ''along with consideration.''

As stated in the proposed rule, the BLM added this paragraph to more explicitly recognize its mandate to manage the Federal lands for multiple use. Stipulations do not prevent oil and gas operations from occurring under a lease. Rather, stipulations that allow, but control, surface use are a valuable management tool to achieve balanced multiple resource use, including oil and gas development. As stated above, the BLM retains discretion in this section and will rely on its expertise when making these site-specific decisions regarding stipulations. Consistent with these objectives, the BLM agrees that the bureau should consider the restrictiveness of a stipulation on operations. In the final rule, the BLM deletes the phrase ''without regard for'' and inserts instead ''while considering'' to recognize the BLM's mandate to manage the Federal lands for multiple use and to provide for the protection of the resources on those lands.

The BLM also received a comment on proposed paragraph (c), which specified that the BLM may attach an information notice to the lease. That comment requested that the BLM remove the last sentence in the paragraph—which reads, ''Information notices may not be a basis for denial of lease operations''—because it undermines the BLM's management authority. Another comment recommended that this paragraph incorporate a requirement that information notices highlight potential conflicts with other resource values and be accompanied by full lease stipulations specifying how those conflicts will be resolved. The final rule does not adopt these recommendations, as the information notice is a method of informing lessees of requirements that may be imposed by an existing law or regulation, not of imposing new requirements.

Finally, the BLM received comments recommending the development of specific stipulations and considerations for all leases, including a no surface occupancy within 2 miles of developed recreation sites and a 1-mile no surface occupancy from key recreation areas. The BLM disagrees and declines to adopt one-size-fits-all stipulations for all leases. The BLM historically has identified the appropriate stipulations through RMPs, ensuring that the BLM ties the appropriate stipulations to the lease under consideration. That approach allows the BLM to develop and set forth lease stipulations in the land-use planning documents/RMPs so that the public is aware of the balance that will exist between environmental protection and opportunities for development of oil and gas resources in advance of offering the lands for lease.

Section 3101.14 Modification, Waiver, or Exception

This section describes the standards that the BLM will use when evaluating modifications, waivers, or exceptions. The BLM proposed changes to the existing § 3101.14 to more explicitly recognize its mandate to manage the Federal lands for multiple use and to provide for the protection of the resources on those lands. The proposed rule also split the existing provision into two components: one to address modifications prior to lease issuance and one for modifications after lease issuance.

The BLM received multiple comments on the BLM's proposed approach. For example, comments: (1) expressed concern that the language broadened the ability of surface management agencies to object to the inclusion of parcels in an oil and gas lease sale; (2) requested a revision to paragraph (a) to state that requests for modification, waivers, or exceptions would not be posted for public comment; (3) suggested the BLM should clarify that this paragraph does not alter or affect criteria for modification, waivers, and exceptions of stipulations in the BLM's RMPs; (4) suggested that the proposed rule introduced new subjective standards, such as a ''major concern to the public;'' and (5) recommended that the BLM should not remove the language ''or if proposed operations would not cause unacceptable impacts,'', since, in the commentors' view, that edit would curtail the BLM's flexibility for addressing circumstances where the BLM's granting of the modification or waiver would not result in unacceptable impacts.

After consideration of these comments, the final rule splits paragraph (a) into two paragraphs for clarity. The first sentence in proposed paragraph (a) now appears at the end of the section in new final paragraph (d), since modifications, waivers, and exceptions to a stipulation are considered later at the APD stage, not at the leasing stage. The restructuring of this provision addresses concerns that the paragraph alters or affects criteria for modification, waivers, and exceptions of stipulations in the BLM's RMPs.

As stated in the proposed rule, the BLM removed the existing provision—allowing the granting of modifications, waivers, or exceptions to lease stipulations if the authorized officer

[10] Proposed regulation text at 43 CFR 3101.13(a): ''The BLM may consider the sensitivity and importance of potentially affected resources and any uncertainty concerning the present or future condition of those resources and will assess whether a resource is adequately protected by stipulation without regard for the restrictiveness of the stipulation on operations.''

determines that the ''proposed operations would not cause unacceptable impacts''—because this authority has been overused [11] and has potentially led to unnecessary adverse environmental impacts.

The BLM has concluded that it is appropriate to exempt situations based on time-sensitive information from the review requirement. For example, if a survey is completed for nesting raptors and it can be confirmed that there are no raptors present, then an exception from a timing stipulation based on the presence of nesting raptors would be appropriate. However, if the 30-day review period applied, the conditions would no longer be in effect to support the exception. Final paragraph (a), which applies to lease terms and stipulations, now states, ''If the authorized officer determines that a change to a lease term or stipulation is substantial or a stipulation involves an issue of major concern to the public, except time-sensitive exceptions based on verified data, the changes will be subject to public review for at least 30 calendar days.'' As stated in the proposed rule, the BLM would consider a change to the lease terms to be substantial if the change would have an important, considerable, consequential, major, or meaningful effect on the environment that was not previously considered, thus requiring public notification (30-day public review) of a lease term or stipulation.

The language in this section does not broaden surface management agencies' ability to object to the inclusion of parcels in an oil and gas lease sale, because lands requiring the consent of other surface management agencies is addressed under § 3101.51. This rulemaking does not introduce new subjective standards. Language such as a ''major concern to the public'' appears in existing regulations and has not caused issues.

One commenter stated paragraph (b) presents potential disruption to the competitive lease sale process as all lease conditions or stipulations must be disclosed prior to a lease sale. The BLM revised this paragraph to reflect IBLA decisions, which have stated that if a lease is issued without prior notice of an additional stipulation, the stipulation is not binding on the potential lessee and is without effect in the absence of the potential lessee's acceptance of the stipulation, see *Emery Energy, Inc,* 64 IBLA 175 (1982). While this rarely occurs, the purpose of this section is to allow the BLM to correct errors made when preparing the Notice of Competitive Lease Sale. Moreover, the MLA vests the Secretary with broad discretion to decide, up until the time of lease issuance, whether particular parcels of Federal land ''may be leased'' for oil and gas development, see 30 U.S.C. 226(a). Under the final rule, the BLM may decide not to issue a lease if the modification of a stipulation could increase the value of a parcel. For example, if the Notice of Competitive Lease Sale incorrectly listed a parcel as subject to a no-surface-occupancy stipulation, and it is then realized that the parcel should not have been subject to that limitation, but this mistake is not caught until after the sale, this could increase the value of the lease. To ensure a fair return to the public, the BLM would decline to issue the lease and would offer the parcel in a future lease sale. The competitive bidding process would ensure that the BLM receives the appropriate bid for the parcel with the modified stipulation.

One comment on paragraph (c) recommended striking the phrase ''was inadvertently omitted,'' and adding ''to comply with a nondiscretionary legal requirement, or to address an adverse effect that was not reasonably foreseeable at the time of lease issuance or whose analysis was otherwise expressly deferred to the site-specific proposal stage,'' and changing ''may'' to ''will'' in reference to lease cancellation. These recommendations would substantially change the meaning of the paragraph, which was intended to address situations when the BLM inadvertently omits a stipulation when preparing parcels for a lease sale. The intent of the modified language is to reflect IBLA decisions on this issue. The BLM has not made any changes based on this comment.

Section 3101.21 Public Domain Lands

The BLM did not propose any changes to the existing § 3101.2–1; however, the BLM received a comment stating that the BLM should not only rely on the section title to convey to readers that the language in the section applies to public domain lands (whereas the next section applies to acquired lands). The BLM concurs with this recommendation and inserts in final paragraph (a) ''on public domain lands.''

Section 3101.22 Acquired Lands

The BLM did not propose any changes to the existing § 3101.2–2; however, the BLM received a comment stating that the BLM should not only rely on the section title to convey to readers that the language applies to acquired lands. Another comment stated that the BLM should specify that the acquired lands limitation is separate from, and in addition to, the limitation for public domain lands. The BLM concurs with these recommendations and inserts in final paragraph (a) ''on acquired lands'' as well as ''separate from, and in addition to, the limitation for public domain lands.''

Federal Lands Administered by an Agency Other Than the Bureau of Land Management

Because of other proposed changes to part 3100, the BLM proposed to redesignate and consolidate the provisions under this heading. The BLM received several comments suggesting that the new definition for ''surface management agency'' under § 3000.5 of this chapter, which includes Interior agencies such as the Fish and Wildlife Service and the Bureau of Reclamation, conflicts with and causes confusion with the provisions under this heading. The BLM concurs and changes the title of this heading from ''Federal Lands Administered by an Agency Outside of the Department of the Interior'' to ''Federal Lands Administered by an Agency Other than the Bureau of Land Management.''

Section 3101.51 General Requirements and Section 3101.52 Action by the Bureau of Land Management

The BLM received numerous comments on proposed revisions, which, collectively, would replicate several paragraphs in the existing regulations requiring the BLM to seek and, in some cases, obtain the consent of surface management agencies prior to leasing acquired or public domain lands into one paragraph. Some comments supported the change. Several comments opposed the change, asserting that it expands the authority of some surface managing agencies, such as the Fish and Wildlife Service and the Bureau of Reclamation, beyond that which is provided under the applicable statute.

The BLM disagrees that the proposed change improperly expands the authority of certain surface management agencies, such as the Fish and Wildlife Service. Instead, this change merely consolidates and clarifies the BLM's duties with respect to prohibitions provided elsewhere in statute or regulation. The BLM has a longstanding practice of consultation with all Federal surface management agencies before authorizing subsurface mineral leasing. For example, the existing regulation at 43 CFR 3101.7–1 recognizes that in some cases the Secretary may lease over the objection of the surface management

[11] See, *e.g.,* GAO–17–307, *https://www.gao.gov/products/gao-17-307.*

agency and in other cases the Secretary may not. Moreover, even where consent is statutorily required, such as on Forest Service lands, the MLA directs that the Secretary of the Interior the Secretary of the Interior ultimately must apply their independent judgement before any leasing may occur. The proposed regulation merely supplies the BLM with the uniform procedures necessary to facilitate these preexisting prohibitions and grants of discretion; it does not enlarge or restrict the BLM's authority. The BLM has added a clause to § 3101.52(b) to clarify that a lack of consent or concurrence will preclude leasing only where provided by law. The BLM has also made certain minor changes for clarity.

Commentors stated that, under the MLAAL, 30 U.S.C. 352, only the head of an executive department has the authority to consent to leasing covered by that statute, such that it necessarily does not embrace ''consent'' by subdivisions of the DOI. The BLM agrees, particularly because the Department's sub-agencies ordinarily enjoy their authority only be virtue of delegation from the Secretary. As set forth above, the proposed text does not alter the balance of authority and discretion among agencies within the Department, but instead simply clarifies that the BLM shall, as a procedural matter, confer with surface management agencies.

Section-by-Section Discussion for Changes to 43 CFR Subpart 3102

Section 3102.20 Non-U.S. Citizens

The BLM proposed to revise the existing § 3102.2 to remove the reference to the outdated term ''alien.'' The BLM received a comment stating that this section should be amended to include more stringent language that would require prospective, non-U.S. citizen bidders, lessees, or interest holders to submit to the BLM a certification of compliance with Federal foreign ownership laws and procedures, including the final rule from the Office of Investment Security, Department of the Treasury, implementing the provisions relating to real estate transactions in section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, prior to the BLM granting such entities a lease. The BLM declines to adopt this change, which is unnecessary. In 1982, the BLM eliminated the requirement for entities to submit documents substantiating their qualifications to hold a lease or an interest in a lease and now requires entities to certify their compliance, including those relating to foreign investment in Federal land, on the lease or assignment application. Any false statements on these documents are subject to the criminal sanctions in 18 U.S.C. 1001 (see 47 FR 8544, February 28, 1982).

Section 3102.40 Signature

The BLM proposed changes to the existing § 3102.4 to clarify that it applies to all applications submitted to the BLM and to allow for electronic signatures. The BLM received a comment in support of the proposal to remove paragraph (b) from this section. The commenter also said the BLM erred, as the submission of three hard copies of any transfer of record title or operating rights is required by the MLA. 30 U.S.C. 187a. The BLM agrees and makes the appropriate changes to the final § 3106.41. The BLM declines to reinstate paragraph (b) in this section to avoid confusion when the BLM starts accepting transfers electronically.

Section 3102.51 Compliance

The BLM proposed revising the existing § 3102.5–1 to clarify who is entitled to hold a lease and that the reclamation obligations under the lease reside with the lessee, operating rights owners, and operators, and not the American taxpayer. The BLM received comments in support of the proposed changes to this section and a recommendation in a comment that the BLM publish and regularly update the list of entities that are not in noncompliance with reclamation requirements of section 17(g) of the MLA. Many comments opposed the proposed changes, citing a lack of due process, fairness, the BLM's ability to take enforcement actions to address any compliance deficiencies, and the need to provide entities the ability to remedy any alleged compliance issues before the BLM turns to cancelling a lease, among other concerns.

To address the comments, the BLM is revising the phrase ''will be subject to cancellation'' to ''may be subject to cancellation'' to clarify that cancellation is only one of the enforcement tools the BLM could apply and allows for due process. As provided under § 3000.40 of this chapter, any decision issued by the BLM pursuant to this section would be subject to appeal. In addition, the BLM updates the list of ''Entities in Noncompliance with Reclamation Requirements of section 17(g) of the MLA'' on an as-needed basis, and then forwards the names of the entities to the Federal Government's suspension and debarment program. *SAM.gov* is a publicly available website that contains the list of suspended or debarred entities. Likewise, when a company returns to compliance, the BLM notifies the suspension and debarment program that the entity should be removed from *SAM.gov*. The BLM declines to publish a duplicate list of these entities. Thus, no further changes are warranted.

Section 3102.52 Certification of Compliance

The BLM proposed a minor change to the existing § 3102.5–2: the removal of the word ''offer'' to reflect Congress' elimination of the noncompetitive leasing process. The BLM received a comment on this section recommending additional language to explicitly state that any false certification is subject to the criminal penalties contained in 18 U.S.C. 1001. The BLM declines to adopt this proposal, which is unnecessary. Section 3000.20 of this chapter already informs all entities that they are subject to criminal penalties if they provide false statements to the BLM. In addition, the standard forms used by the BLM under these regulations, such as the bid form (3000–002), assignment of record title form (3000–003) and the transfer of operating rights (3000–003a), and the lease form (3100–011), all include similar statements and references to 18 U.S.C. 1001 for any false statements.

5. Section-by-Section Discussion for Changes to 43 CFR Subpart 3103

Section 3103.1 Fiscal Terms

The BLM removes the proposed § 3000.130 from the final rule and moves the information in that section into final § 3103.1, since this section addresses oil and gas fiscal terms and does not impact other minerals management programs. Therefore, the BLM determined that it is more appropriate to codify this section in subpart 3103 instead of part 3000. As a result of this change, the BLM updated all cross references in the final rule from § 3000.130 to § 3103.1.

Based upon the comments received, the BLM also incorporates additional updates that include: (1) adding the EOI filing fee from the IRA to this section and (2) changing the timeframe that the BLM will adjust the fees for inflation from annually to once every 4 years.

First, the BLM moved the new EOI filing fee, established by the IRA, from proposed § 3000.120 to final § 3103.1(a). The BLM cannot update the EOI fee annually. The MLA at 30 U.S.C. 226(q)(2)(B) states, ''The Secretary shall, by regulation, not less frequently than every 4 years, adjust the amount of the fee under subparagraph (A) to reflect the change in inflation.'' Therefore, the final

rule moves the EOI fee to paragraph (a). Second, the EOI fee will be adjusted every 4 years by way of a final rule as part of the new Fiscal Terms Table. The BLM also changed the adjustment for minimum bonus bids and rentals to be adjusted every 4 years for inflation by way of a final rule. This change will allow the final rule to update these terms to occur at the same time and minimize the public's costs for these inflation adjustments. The BLM also renamed the title of this section from ''Fiscal terms of new leases'' to ''Fiscal terms.''

One commenter stated that the BLM should tie all costs and returns associated with oil and gas leasing to an inflation index. The BLM did not make any changes in response to this comment, as all fees in § 3000.120, the fiscal terms in § 3103.1, and the minimum bond amounts are tied to changes in the Implicit Price Deflator for Gross Domestic Product, which is published quarterly by the U.S. Department of Commerce. Finally, a comment stated that the BLM should clarify that the inflation adjustment as described in this section will include adjustments for inflation occurring over any period of multiple years after August 16, 2022, during which bid and rental rates were left unchanged despite inflation. The BLM concurs with this recommendation, which is reflected in the existing regulations and its use of the Implicit Price Deflator for Gross Domestic Product.

Another commentor stated that the proposed rule references no authority that would support annual inflation adjustments for the rental and bonus as the IRA precludes the adjustment of these fiscal terms until after August 16, 2032. The BLM agrees that the rental and minimum bonus bids must remain at the current rate until August 16, 2032; however, after this date, the IRA changes these amounts to minimums. Therefore, the BLM proposed and is implementing inflation adjustments for rental amounts and minimum bonus bids after August 16, 2032. To reduce confusion, the BLM updates paragraph (a) by adding the sentence, ''Per the Inflation Reduction Act, the BLM will not adjust the rental nor the minimum bonus bids until after August 16, 2032.''

Section 3103.12 Where Remittance is Submitted

The BLM proposed to update the existing § 3103.1–2 to clarify that fees set out in the fee schedule in § 3000.120 of this chapter and all first-year rentals and bonuses for leases issued under 43 CFR part 3100 must be paid to the proper BLM office. This final section also removes outdated references to the former Minerals Management Service and mailing address for payments. The BLM received a related comment on lease reinstatements, in which the commenter stated that references in the BLM regulations to rental payments through the ONRR's online system should also acknowledge ONRR's continuing practice of accepting non-electronic rental payments in some circumstances. The BLM concurs and changes the language in paragraph (a)(2) from ''through its online system'' to ''refer to 30 CFR 1218.51'' that lists the methods by which lessees and operators may submit payments to the ONRR.

Section 3103.21 Rental Requirements

The BLM requested comments on adding a new requirement for diligent development obligations.

Comments that supported a diligent development provision included recommendations that the BLM: (1) implement further leasing reforms, such as increasing production from existing leases by ensuring diligent development, implementing specific diligent operations standards, and adopting a mechanism to hold private companies accountable when they fail to meet the requirements; (2) tie the diligent development requirement to the definitions of ''qualified lessee,'' ''responsible bidder,'' and ''responsible lessee;'' and (3) impose a diligent operator standard with reporting requirements, and absent a rental rate increase, clarify what consequences an operator may face when it fails to operate diligently including lease termination. Comments also asserted that the proposed lease rentals are insufficient and leases that are not pursued for development within 5 years should be permanently revoked and should not be transferable to another entity.

Comments that opposed a diligent development provision included statements that: (1) failure to act diligently to develop a lease has no adverse impacts on the environment; (2) adding diligent development obligations would result in additional work for the BLM and an unnecessary burden on lessees; (3) the increased rental rates prescribed by Congress in the IRA and adopted in the final regulations will encourage diligent development on their own and encourage prudent development or lease surrender; (4) the diligent development obligations would impact business decisions that are based on markets, investment capital, supply chains, labor and equipment availability, and other factors; (5) geophysical exploration does not always result in lease development; (6) new diligent development terms would impose large cost increases on many leases and inhibit operator flexibility to properly evaluate and commence operations in a responsible developmental situation and economic manner consistent with lease requirements; (7) a diligent development requirement could exacerbate the climate crisis; (8) the BLM should consider delays that are out of an operator's control, such as the time certain Federal processes or lawsuits can take; (9) the proposed rule's list of alternatives is overly lenient and promotes speculative ventures; and (10) the BLM should not apply too broad an interpretation of diligent development.

After careful consideration of the comments received, the BLM did not implement a diligent development requirement with an escalating rental rate in the final rule. The BLM believes the existing increasing rental rates prescribed by Congress in the IRA will encourage diligent development on their own by incentivizing lessees and operators to develop a lease to avoid the increased costs. The BLM will continue to assess the oil and gas leasing program, and if the BLM determines Congress' rental rate increases are not as effective as expected at encouraging diligent development, the BLM may consider additional rulemaking. The BLM further clarifies final paragraph (a) by adding, ''for that lease'' after the words ''total acreage'' to clarify the basis for calculating the first-year rental. No further changes have been made to this section.

Section 3103.22 Annual Rental Payments

The BLM proposed changes to the existing § 3103.2–2 to implement changes made by Congress in the IRA and clarify what constitutes a timely payment of rental by tying the payment to the lease anniversary date. The BLM received numerous comments on this section. The comments encouraged the BLM to: (1) set out the actual required rental amounts, as provided by the current regulations, rather than referring to the lease terms; (2) set a policy determining when rental rates should be higher than the statutory minimums; (3) implement the regular rate increases; and (4) further increase the rental rates, on the theory that the rental rates in the IRA are too low.

In the IRA, Congress set rentals at $3 per acre, or fraction thereof, for lease years 1 and 2; $5 per acre, or fraction thereof, for years 3 through 8; and $15 per acre, or fraction thereof, thereafter. Ten years after the enactment of the

IRA, those rental rates become minimums and are subject to increase, as discussed in § 3103.1. The BLM agrees with the comments that the section in the proposed rule was not clear and adds the following clause at the end of paragraph (a) ''the annual rental for all new leases will be as specified in 43 CFR 3103.1.'' 43 CFR 3103.1 sets out the actual required rental rate, provides details on when the BLM will increase the rental rate, and implements a rate increase every 4 years. The BLM cannot increase the rental until August 16, 2032, based upon Congress' direction in the IRA.

Another comment objected to the application of these rentals to leases sold before the passage of the IRA but issued after the IRA was signed into law. The commenter explained that companies bid on those parcels relying on the rental and royalty rates that were in effect at the time of the lease sale and contended that lease issuance was only delayed due to the BLM's failure to timely resolve protests.

As explained in the preamble to the proposed rule, the IRA amended the rental rate for all new oil and gas leases *issued* in the next 10 years. Because the statute ties the new rates to lease issuance, the BLM does not have the authority to exempt leases sold but not issued prior to the enactment of the IRA from its terms.

Section 3103.31 Royalty on Production

The BLM proposed changes to the existing § 3103.3–1 to implement the requirements of the IRA and received numerous comments.

Supportive comments recommended that the final rule address plans, specify criteria, or include a procedure for increasing the royalty rate after 2032. These comments suggested various ways to implement this recommendation, including codifying a higher royalty rate of at least 18.75 percent, or 20 percent; increasing the royalty rate consistent with the previous 10-years' worth of inflation, but not deflation, and indexing the royalty rate to raise at prescribed intervals; or adjusting all rates to market levels on a regular basis to better ensure fair return. Supportive comments also requested a termination provision, similar to that for failure to pay rentals, for the failure to pay royalties. Other supportive comments stated that the BLM should limit changes to just those required by the IRA, as the new rate could affect the competitiveness of the U.S. minerals program.

Comments that opposed the changes included statements that: (1) higher royalty rates have consistently led to increased revenues without discouraging oil and gas development and the new rate of 16.67 percent is still well below the rate that is charged for offshore drilling in Federal waters (18.75 percent) and imposed by leading oil-and gas-producing States, including Texas (20–25 percent), Colorado (20 percent), and New Mexico (18.75 to 20 percent); (2) the final rule should refrain from setting a minimum rate because the cost of operating on Federal lands is higher than on State or private lands, and a higher royalty will make it uneconomic to operate on most Federal lands; (3) the higher minimum, and any increased royalty rate, will disincentivize operations on Federal lands, harming small business, local governments, and States; (4) the BLM failed to provide a justification for making the royalty rate the minimum, and the bureau should consider establishing 16.67 percent as the maximum with a mechanism for determining a lower rate when the 10-year statutory requirement expires; (5) the BLM should not comply with the IRA's mandate or adopt a permanent royalty relief rule for onshore production; (6) raising oil and gas royalty rates will directly reduce well operators' revenue margins, risking well closures and deliberate attempts to devalue oil fields; (7) higher royalty rates affect long term project economics by reducing the expected revenue and making them less financially feasible; (8) higher rates will deter small operators from investing in expensive enhanced oil recovery methods that can extend the productive life of a well; and (9) raising the Federal royalty rate encourages cheating and requires greater Federal investment in compliance enforcement at taxpayer expense.

As stated in the proposed rule, the BLM updated this section to implement IRA section 50262, which set royalty rates at 16.67 percent for the 10 years following the Act's enactment. Final paragraph (a)(3) of the regulation states that for leases issued after the 10-year period following the passage of the IRA, the royalty rate will be not less than 16.67 percent, which is the rate Congress required in the IRA. The BLM declines to set post-2032 rates now (or to implement associated procedures) so far in advance of any authorized increase. However, the BLM may consider further adjustments after 2032. The BLM also declines the suggestion to implement an automatic termination provision for the nonpayment of royalties. The procedures for lease forfeiture and cancellation are set forth in section 31(a) of the Act (30 U.S.C. 188) and § 3108.30(b) of the regulations. The BLM adopts this section into the final rule without any further changes.

Section 3103.41 Royalty Reductions

The BLM proposed revising the existing § 3103.4–1 to clarify that production in paying quantities is a prerequisite to obtaining royalty relief under this section. The BLM also solicited feedback to improve the royalty rate reduction section.

Comments recommended that the BLM: (1) describe the specific circumstances for justifying a reduction and clarify that the reductions will terminate as soon as the conditions justifying the reduction have passed; (2) explicitly state that a royalty rate reduction would transfer to the new lessee when a lease is assigned; (3) provide specific criteria for lowering the rate; (4) set a limit on the lower end of the reduced rate; (5) limit the period for the reduction to apply; (6) specify that reduced royalties transfer to assignees only on a case-by-case basis; (7) extend royalty relief to all producers at any point of production; (8) extend the royalty relief to any field where operators are seeking to conduct or are conducting waterfloods or other enhanced oil recovery methods; (9) not set a floor for royalty reductions because a universal rate, even a low one, cannot account for the varying productivity within a formation; (10) determine the royalty relief by the field productivity and the crude grade produced; (11) determine the appropriate royalty rate reductions based upon a critical review of the economic data for reasonableness and clearly enumerate the costs that are allowed for the economic evaluation to ensure operators send unbiased data; (12) closely monitor any approved royalty reduction; (13) clearly define under what circumstance/criteria royalty reduction terminates; (14) revise the phrase ''royalty reductions at the discretion of the Secretary'' to convey that reductions are the exception, not the norm; and (15) add language to require notification to the State when royalty reductions take place, given the State's interest in the royalty rate and the economic health of the industry and local communities.

The BLM rarely grants royalty rate reductions, and after careful review of the comments, has decided against making any further changes. The regulation states that the Secretary may waive, suspend, or reduce the rental or royalty upon a ''determination that it is necessary to promote development or that the leases cannot be produced in paying quantities under the terms provided therein.'' Thus, the BLM only

grants a reduction in royalty rate if the operating costs exceed the gross income. Otherwise, the BLM would deny the royalty rate reduction. The regulatory requirements reflecting these parameters come directly from the statutory authorization for royalty reductions at 30 U.S.C. 209. Additionally, if the operating costs would still exceed the gross income with a royalty rate reduction, the BLM must consider terminating the lease for no longer being capable of production in paying quantities under 43 CFR 3107.22.

The factors the BLM considers when evaluating a reduction are case-specific, and the BLM must review each application. Given this and the exceptional nature of circumstances that may warrant royalty reductions, the BLM declines to further specify the circumstances or specific criteria for lowering a royalty rate in the regulation in order to retain the discretion of the authorized officer to address case specific situations that may occur. The BLM is committed to adhering to the existing rules and policy and will ensure that they are consistently and faithfully applied to future royalty relief applications.

Second, the BLM declines to codify language stating that a royalty rate reduction would transfer to a new lessee when a lessee assigns its lease. The operating costs for the lease may change with the new lessee; therefore, the BLM would need to complete a new review to determine if the royalty rate reduction is appropriate.

Third, some commenters opposed and some supported implementing a lower limit for royalty reductions, but no lower limit was proposed. The BLM has decided not to implement a lower limit and will instead continue to rely on the economics of each lease to determine the appropriate royalty reduction, if warranted.

Fourth, the BLM will not provide royalty relief based only upon operators conducting or seeking to conduct waterfloods or other enhanced oil recovery methods. These operations will return a profit to the operators and in most cases a royalty reduction would not be appropriate as the gross income exceeds the operating costs.

Fifth, the requirements to monitor royalty rate reductions or to send notice to States are better suited to be addressed through policy as these requirements would apply only to the BLM and not the regulated community. The BLM already tracks royalty rate reductions in MLRS and will continue to closely monitor reductions. Given how rare royalty rate reductions are, the BLM has not established a requirement to notify the States. The BLM will consider whether a notification to the States should become a matter of policy in the future.

Sixth, the existing regulations and Bureau policy reserve the BLM's right to terminate a royalty reduction, re-adjust the amount of reduction, or restore the royalty rate to the rate required by the lease terms and/or regulations at any time for the entire lease or for any portion thereof. Given that the grant of a royalty rate reduction is uncommon, the BLM is declining to add any blanket provisions to the regulations that would remove this flexibility. For example, the BLM may need to terminate relief retroactively if such relief was based on manipulation of normal production or adulteration of oil sold.

Sections 3103.42 Stripper Well Royalty Reductions and 3103.4–3 Heavy Oil Royalty Reductions

The BLM proposed to eliminate both of §§ 3103.4–2 and 3103.4–3 in their entirety because they are obsolete for the reasons described below. The BLM received a comment stating the BLM's removal for obsolescence ignores the fact that over the next decade, the number of stripper wells on Federal lands will rise along with necessary oil exploration and production.

As stated in the proposed rule, the BLM revised both sections on October 6, 2010 (75 FR 61624), to eliminate these types of royalty relief, because Congress enacted separate relief in section 343 of the Energy Policy Act of 2005 (42 U.S.C. 15903). However, the BLM retained the regulations because, while these types of royalty relief were no longer available for current production, prior production subject to this relief continued to be subject to audits. This is no longer the case; therefore, these provisions serve no purpose. To the extent relief is required in the future, the BLM would promulgate any necessary regulations under section 343 of the Energy Policy Act of 2005 rather than relying on these provisions. In addition, the BLM has the authority under section 39 of the MLA to waive, suspend, or reduce the royalty for a lease.

Section 3103.42 Suspension of Operations and/or Production

The BLM proposed redesignating this section from 43 CFR 3103.4–4 to 43 CFR 3103.42 and clarifying how a lease term will be adjusted once the suspension ends.

The BLM received a comment on paragraph (a) stating that the BLM should broaden the circumstances for which a lease would be eligible for a suspension of operations only or a suspension of production only beyond force majeure, or at a minimum should acknowledge that the BLM's own delays constitute such a force majeure for the purposes of these types of suspensions. The regulations clarify that a force majeure is ''matters beyond the reasonable control of the lessee.'' Because this encompasses an administrative delay, the BLM already takes such delays into consideration when evaluating a suspension. The BLM is not revising the regulation to further specify instances that may be considered force majeure; BLM Manual 3160–10, *Suspension of Operations and or Production,* provides further examples of acts constituting force majeure.

Some comments stated that lease suspensions, whether requested by the lessee or directed by the BLM, should be made public as soon as they are submitted and should be subject to public review and comment in accordance with NEPA. The BLM disagrees with this recommendation. NEPA is only triggered if there is a proposal for a major Federal action that potentially affects the environment. Although the approval or direction of a suspension is a Federal action, lease suspensions are categorically excluded from NEPA review as administrative actions taken on an already existing authorized lease. See the BLM's National Environmental Policy Act Handbook H–1790–1, Appendix 4.[12]

Some comments stated that the BLM should clarify that both the suspension request and the decision by the BLM must be made in writing and published on a BLM website, and that the proposed rule fails to provide the transparency and public access to information about lease suspensions that is guaranteed by the Administrative Procedure Act. The BLM disagrees with this comment, as suspension decisions have always been publicly available through review of the case file located in the relevant BLM state offices or through the BLM's reporting application at *https://reports.blm.gov/reports/MLRS.*

Another comment stated that the BLM should clarify in paragraph (d) that any lease production is prohibited while a suspension of operations and production is in effect. The BLM agrees, and it is BLM policy that production from a lease is prohibited if there is a suspension of operations and production. *See* BLM Manual Section 3160–10, *Suspension of Operations*

[12] *https://www.blm.gov/sites/blm.gov/files/uploads/Media_Library_BLM_Policy_Handbook_h1790-1.pdf.*

and/or Production.[13] The rule provides that ''if there is any production sold or removed during the suspension, the lessee must pay royalty on that production.'' This statement covers instances where there are no operations or production, but the operator sells already existing product captured prior to when the suspension went into effect; it does not supersede the ordinary bar on production during suspensions, and merely ensures the lessees pay royalty on that sold production.

Multiple commenters stated that the BLM should: (1) clarify that lease suspensions are the exception and not the rule; (2) provide limited and specific criteria that would justify a suspension; and (3) offer guidance on how the BLM plans to deal with existing lease suspensions. The BLM declines to modify the regulations as detailed in the three comments above. The MLA provides direction, and the BLM has set guidance on when a lease suspension is appropriate. First, the BLM currently has approximately 3,000 suspended leases of the over 33,000 authorized onshore oil and gas leases. While suspensions are not a common occurrence, the number of lease suspensions has increased based upon the large number of leases litigated in court after lease issuance over the past decade. Second, the BLM declines to provide limited and specific criteria in the regulations. The BLM provides guidance to its employees in IMs and MS–3160–10, *Suspension of Operations and/or Production.*[14] The BLM declines to make this change at this time to retain the discretion of the authorized officer to address unique situations that may occur. Third, the BLM already established guidance on how the BLM plans to deal with existing lease suspensions in Permanent IM 2019–007, *Monitoring and Review of Lease Suspensions;*[15] therefore, the BLM declines to add this information into the regulations. The existing regulations require evaluation of lease suspensions on a lease-by-lease basis. Reviews of existing lease suspensions are currently addressed in the BLM's policy IM 2023–012, *Suspension of Operations and/or Production* [16]. No changes have been made in the final rule to avoid limiting the discretion of the authorized officer to address unique situations that may occur. For example, litigation or actions of Federal or State agencies that prevent commencement or continuation of operations may be applied to suspensions granted under section 17(i) or section 39 of the MLA depending on the unique circumstances of the case.

A commenter was concerned that changing the word ''terminating'' in existing paragraph (e) to ''lifting'' in final paragraph (g) will be interpreted by lessees and others to require the BLM to take affirmative action to end a suspension. The comment states that a lease suspension should lift automatically—without any subsequent administrative action by the BLM—when certain regulatory events occur or as otherwise stated in the approval letter, and the BLM should avoid any change that would increase the administrative burden on the agency. The BLM disagrees with this comment. While it is true that, in some cases, the BLM's decision to suspend a lease will document a particular event or action that will eventually lift a suspension, the BLM always issues a decision for the official record when lifting a suspension, allowing for the expiration date of the lease to be properly adjusted and facilitating any reconciliation of the rental amount that may be due, see *C.W. Trainer,* 69 I.D. 81 (1962). A copy of that decision is sent to ONRR to notify it of a change in the status of the lease. The final rule did not change this process. Based upon a review of the comments received, the BLM did not make any changes for this section from the proposed rule: the process described above is consistent with the term ''lifting'' as the term avoids confusion and leads to an understanding that the BLM takes an action to end a suspension.

Section-by-Section Discussion for Changes to 43 CFR Subpart 3104

In subpart 3104, the BLM proposed to revise its bonding regulations by increasing the minimum amount of bonds, removing nationwide and unit operator bonds, adding surface owner protection bonds, and removing letters of credit (LOCs) and CDs as options that lessees can use to secure the required bond amounts. The BLM received several comments on the proposed bond amounts. Some comments supported the higher amounts, with some stating these amounts do not reflect the full reclamation costs of oil and gas wells. Other commenters recommended the final rule establish a full-liability, individual lease bond or tie the bond amount to the number of wells covered by a bond. The MLA does not require the BLM to impose full cost reclamation bonds but does require the Secretary to ensure the bonding is adequate to ensure reclamation. Requiring a full liability bond would require increased staffing at the field and state offices to manage increased workloads for the review of changing conditions and the adjudication of additional bond riders to either raise or reduce the bond amount. In addition, the BLM's APD processing time would slow due to waits for additional bond riders. The BLM has opted to keep to a higher minimum bond amount and depend upon its policy guidance and future adjudications for increasing the bond amount for specific operations that pose additional risk, which will allow the BLM to direct its limited resources to where they can have the most impact.

Comments also recommended that the BLM review its average costs for reclaiming orphaned wells, noting that the States have identified a higher average cost for their orphaned wells. The BLM reviewed its costs related to cleaning up orphaned wells that were plugged since the BLM calculated the average cost as part of this rulemaking effort. Due to the limited number of additional orphaned wells that have been plugged in that time, there is not enough additional data to warrant a recalculation. Therefore, the BLM did not adjust the minimum bond amount based on a new average orphaned well cost.

Some comments stated the BLM should not have used the median number of wells to determine the new minimum bond amounts but rather should have considered the probability of the number of wells to be orphaned. The BLM is unable to predict whether any particular well will become an orphan well due to many factors that can lead to a well becoming orphaned (*e.g.,* operator's revenue stream, operator's cost stream, current regulatory framework within the State, remaining oil and gas reserves, etc.) and the lack of data for each of these factors. Therefore, the BLM lacks the necessary information to determine the probability of a well to become orphaned and thus did not use it as a basis to calculate bond costs.

Several comments opposed the higher minimum bond amounts and requested that the BLM remove the proposed bonding changes, explaining that the BLM rarely needs to access a bond to plug a well. Comments also asserted that the BLM's own statistics do not justify the bonding provisions in light of the MLA's requirement for an adequate bond. As stated in the proposed rule, the minimum bond amounts have not been increased since 1951 (for statewide and nationwide bonds) and 1960 (for lease bonds), have been repeatedly

[13] *https://www.blm.gov/sites/default/files/docs/2022-03/MS-3160-10%20Rel.%203-150.pdf.*

[14] *https://www.blm.gov/sites/default/files/docs/2022-03/MS-3160-10%20Rel.%203-150.pdf.*

[15] *https://www.blm.gov/policy/pim-2019-007.*

[16] *https://www.blm.gov/policy/im-2023-012.*

found inadequate by the GAO and the OIG, and are no longer adequate to provide the requisite funding for reclamation when a lessee defaults on its obligations.

The BLM received several comments stating that the higher minimum bond amounts will be a significant financial burden on operators and small businesses, because sureties often require companies to post cash or security collateral. The BLM disagrees. The Small Business Administration (SBA) helps small businesses guarantee performance bonds issued by certain surety companies, which allows the companies to offer surety bonds to small businesses that might not meet the criteria for other sureties. The SBA's website states that all performance bond guarantees require small businesses to pay SBA a fee of 0.6% of the contract price. The operator would need to make a payment of $900 for an individual bond or $3,000 for a statewide bond to SBA, which would allow the small entity to obtain a surety bond without requiring the company to post cash or security collateral. The BLM encourages small businesses and operators to reach out to the resources available to them including those provided by the SBA and visit their web page: *https://www.sba.gov/funding-programs/surety-bonds.*

In addition, the BLM conducted a review of small entities operating on Federal oil and gas leases based upon public data. If these companies paid sureties 3% of the additional bonding cost annually, their overall cost-to-revenue ratios would increase by less than one-tenth of one percent. If these companies instead chose to fund the full bonding amount out of revenues, their cost-to-revenue ratio would increase by at most 1.4% for one year. Based upon our analysis, the BLM certifies that there will not be a significant economic impact on small entities in the RFA; refer to section V.B. Please also review the RIA for more information.

Section 3104.1 Bond Amounts

Based upon the comments received, the BLM decided to implement inflation adjustments for minimum bond amounts. The BLM completed this action by (1) adding the minimum bond amounts to this section to provide for inflation adjustments; (2) moving the phase-in period for lease and statewide bonds into this section; (3) providing a longer implementation for small operators to increase or replace their bonds; and (4) providing information to operators on the penalties they could incur if they fail to increase or replace existing bonds that do not meet the new minimum bond amounts.

First, the BLM requested comments on whether it should adjust the minimum bond amounts to keep up with inflation. The BLM received multiple comments recommending the BLM periodically adjust the minimum bond amounts to better protect the taxpayer's interests in adequate reclamation. The BLM agrees with these comments and updates the final rule to include inflation adjustments to bond amounts by way of a final rule and titled this § 3104.1 ''Bond amounts.'' This update will allow the BLM to periodically update bond amounts based upon the rates of inflation.

Second, the BLM moved the phase-in period for statewide and individual bonds from proposed § 3104.90 to final § 3104.1(c). The phase-in period for lessees to replace unit and nationwide bonds remains in final § 3104.90. This change allows the BLM to easily update the phase-in periods for individual or lease bonds and statewide bonds upon adjusting the minimum bond amounts for inflation. The BLM anticipates that when the minimum bond amounts are adjusted for inflation in the future, the phase-in periods will occur over 2 years:

- One year for statewide bonds, and
- Two years for individual bonds.

This phase-in follows the initial proposed timeframes. The BLM has calculated the staffing needs required to process all bond increases for a 1-year phase-in period and concluded the BLM will require 2 years to provide sufficient time to ensure all bonds are brought into compliance.

Third, the BLM considered comments regarding the impact to small operators from increasing the minimum bond amounts. Larger companies usually hold nationwide or statewide bonds, while smaller companies usually hold individual bonds. Initially, the BLM proposed to require individual bond holders to come into compliance with the new bond amounts first. Commenters expressed concerns that the higher minimum bond amounts may force small operators out of business. To alleviate some of the concerns expressed by commenters with respect to the impact on small operators and given the large number of individual bonds, the BLM has revised the final paragraph (c) to give those with individual bonds more time by phasing in this requirement over a 3-year period, instead of over a 2-year period. The longer phase-in period for individual bonds will provide more time for smaller operators, who predominantly rely on individual bonds, to research and obtain the appropriate bond amount. When minimum statewide and individual bond amounts are adjusted for inflation in the future, the BLM anticipates the shorter phase-in periods (2 years for individual bonds) will be sufficient for all bond holders to come into compliance because the bond amount increase will not be as significant a change.

A comment expressed concern regarding which penalties could accrue to lessees who do not increase the bond amounts within the time allowed. The BLM reviewed its existing regulations and added a new paragraph (d) to this section to address this comment. Paragraph (d) now refers to the existing regulations that the BLM may use if an operator fails to increase or replace an existing bond as required by the regulations. The potential penalties include shut down of operations under 43 CFR 3163.1(a)(3), lease cancellation under 43 CFR 3108.30, or referral of the obligor or principal to the Department's Suspension and Debarment Program under 2 CFR part 1400.

The BLM considered shorter timeframes for inflation adjustments to the minimum bond amounts, including annual adjustments, but concluded that shorter timeframes are unworkable given the BLM's workload associated with possible enforcement. Instead, the BLM has opted to update the minimum bond amounts in the final § 3104.1 table every 10 years. The final rule for the updated bond amounts in the 3104.1 table will also indicate the new deadlines for compliance. This 10-year timeframe will provide sufficient time for entities to come into compliance, for adjudication of the financial assurances, and for the BLM to ensure such compliance prior to the implementation of new minimum bond amounts.

The BLM received other comments related to adjusting the fiscal terms for inflation. One commenter stated that the BLM should not attempt to automatically adjust existing bonds for inflation without the surety's consent. The phase-in periods will provide time for the bonded principal to work with the surety to increase the amount or replace the bond. Another commenter recommended that the BLM conduct annual reviews and commit to increases in line with larger economic trends and not just inflation. The BLM will move forward with updating the minimum bond amounts based upon inflation every 10 years as part of the final rule; however, the BLM maintains the right to conduct reviews of bonds to determine if additional increases are necessary and in the public interest.

Section 3104.10 Bond Obligations

The BLM requested comments on the proposed revisions to § 3104.1 along with any supporting information on whether the final rule should provide for any other types of financial arrangements that the BLM should consider.

The BLM received several comments stating the BLM should not eliminate CDs and LOCs from the options available to satisfy bonding requirements, reasoning that the elimination would impose an unwarranted burden on lessees and operators, particularly small operators, and that the BLM should provide more options to post the bonds rather than eliminating options.

Based on the comments, the BLM has decided to reinstate CDs and LOCs as acceptable forms of security for a personal bond. To resolve some of the issues that led the BLM to propose eliminating the securities, the BLM made changes to the regulations for CDs and LOCs. Given that CDs are now issued electronically by banks, they do not meet the existing requirement that Secretarial approval be indicated on the face of the document. Therefore, the BLM modifies paragraph (c)(1) for CDs by inserting ''or through assignment'' to provide for Secretarial approval prior to any redemption.

The BLM modifies paragraph (c)(5) for LOCs to change ''shall'' to ''must'' or ''will'' as appropriate and consistent with the similar changes made in the proposed rule. The BLM also removes the language ''the deposits of which are federally insured,'' as this phrase in the existing regulation has caused confusion to both operators submitting a bond and BLM staff who review bonds and their associated securities. The $250,000 Federal deposit insurance limit for deposits that a person may have with a financial institution does not apply to LOCs, because the guarantee of payment under a LOC is made by the financial institution directly to the BLM by demand, see 31 CFR part 28.204–3(b). LOCs are not depositor accounts to which the Federal Deposit Insurance Corporation (FDIC) insurance applies. Therefore, the BLM is not concerned with FDIC insurance when the amount of a LOC exceeds the FDIC limit.

Paragraph (c)(5)(ii) is modified to appropriately reference the types of bonds as ''an individual lease or statewide bond,'' and to change the term ''attachment'' to ''collection'' for clarity.

Paragraph (c)(5)(v) is modified to state, ''In the event the BLM is notified of the financial institution's intent not to renew the letter of credit, the principal must extend the letter of credit or provide an adequate replacement bond with an assumption of liability rider. If the BLM does not receive an adequate notice or replacement bond with rider, the BLM will collect the letter of credit within 30 days of the expiration without further notification to the obligor.'' The BLM is including this language to ease the administrative burden that results if an entity fails to maintain the LOC. Previously, when an entity failed to pay the premiums to the bank, the BLM, in turn, had to notify the obligor (the bonded party) to replace the bond within 60 days; monitor the timeframes to ensure the LOC is extended or replaced; adjudicate an acceptable form of replacement security or bond; and send a demand to collect on the letter of credit when all else fails. The new language will reduce the BLM's workload by obviating the initial notice to the obligor to replace the bond. To be clear, the BLM will send a demand to the bank to collect the funds from the LOC 30 days prior to the expiration date without further notice of the action from the BLM when the obligor fails to take corrective action on their own accord.

For other types of financial guarantees, one commenter recommended that the oil and gas program review the bonding requirements and language of the BLM's solar and wind energy regulations in 43 CFR 2801.5(b) for consistency, especially language regarding whether corporate guarantees are an acceptable or unacceptable bond instrument. Another commenter stated that alternative financial arrangements could include insurance policies as both an alternative and to complement surety bonds such as insurance accounts to pre-fund decommissioning costs, where sureties direct a portion of their annual premiums and payouts could be made to the operator or the BLM upon default.

The BLM carefully considered the comments and other forms of financial assurance to secure bonding and is declining to include any other forms of financial assurance because the BLM believes the current list, with the retention of LOCs and CDs, is sufficient. The BLM reviewed BOEM regulations, which provide for corporate guarantees, insurance, decommissioning accounts, and other forms of security approved by the Regional Director. The BLM also reviewed the solar and wind energy regulations, which provide for the same financial assurances listed in this final rule as well as insurance. As discussed below, the BLM has decided not to allow corporate guarantees and insurance as means to satisfy the bond requirements. The BLM has determined that corporate guarantees are not an acceptable form of bond security given the need to continually confirm the viability of the corporate guarantee. The BLM does not have the staff or expertise to perform this function, and, without the ability to closely monitor the financial stability of the corporation providing the guarantee, there is a risk the company may default or go bankrupt during the term of a lease, before plugging and reclamation of the existing well(s) and disturbance. To secure a replacement bond at that time would be difficult, if not impossible, thereby potentially leaving the Federal taxpayer to foot the bill for any necessary reclamation.

While insurance is an acceptable form of bond security used in other BLM programs, the BLM declines to use insurance for the oil and gas program given the risks and increased administrative workload for the following reasons.

First, the basic principle of insurance is the transfer of risk. It transfers the risk of financial losses as a result of specified but unpredictable events to an insurer in return for a fee or premium. While insurance is acceptable for unforeseen events such as spills or accidents, the BLM's performance bond secures the promise to fulfill a known, contractual obligation an entity has undertaken to perform at some point in the future.

Second, an insurance policy is usually a written contract between two parties, the policyholder (the person or company that gets the policy) and the insurer (the insurance company). The BLM would be a third-party beneficiary under this scheme, and considered appropriate language to that effect, but this arrangement is still significantly different from surety bonds where there is a contract between three parties (the BLM, the principal (or bonded party), and the surety where the BLM is a party to the agreement). Therefore, the BLM would hold more risk because it is not a party to the insurance.

Third, generally, either party to an insurance contract may cancel the contract unilaterally. To address this, the BLM considered regulatory language stating, *e.g.,* that policy must be non-cancellable. However, this could cause confusion with cancellation of a bond since existing § 3104 does not provide for canceling or releasing oil and gas bonds and the only time a bond is canceled is by a court order. The regulations only provide for terminating the period of liability on the bond.

The BLM believes the revised regulations provide sufficient options

for the regulated community to meet the bonding requirements, and, for all the reasons stated above, the BLM has determined not to rely on insurance for bonding.

As mentioned above, BOEM's bonding regulations at 30 CFR 556.900 allow for the provision of ''Another form of security approved by the Regional Director.'' 30 CFR 556.902(e)(3). The BLM recognizes this option provides a level of flexibility that is not present in the BLM's regulations. However, the BLM has decided to refrain from including a similar provision in its regulations because the BLM does not have staff to implement such a provision. As of May 1, 2021, BOEM managed about 2,287 active oil and gas leases on approximately 12.1 million acres, while the BLM managed 35,871 leases on approximately 24.9 million acres. The BLM manages significantly more leases and significantly more bonds with no staff solely dedicated to bond adjudication. Instead, the BLM staff adjudicate both bonds and post-leasing actions. Therefore, the BLM does not have the staff nor expertise to implement a provision similar to 30 CFR 556.900.

The BLM considered decommissioning, abandonment, or trust accounts that can only be drawn upon to cover decommissioning expenses. Similar to corporate guarantees, allowing the use of these types of accounts would require continual review of constantly changing conditions and the expertise that BLM staff lack.

Some comments stated the BLM should require additional criteria for surety companies to ensure that bonded amounts will be available to the regulator if, and when, the operator defaults. The commenter recommended that the BLM should adopt additional criteria that (1) consider a surety's existing aggregate risk when determining whether that surety qualifies for certification, and (2) impose an underwriting limitation on the aggregate risk of all bonds issued by a surety. The BLM declines to make this change because the Department of Treasury already reviews the underwriting limitation and requires an excess risk reinsurance to protect the Federal Government. Please see Department of the Treasury Circular 570 for more information.

Section 3104.20 Lease Bond

For the existing § 3104.2, the BLM proposed changing the specifications regarding who must post a bond to state that the operator must be covered by a bond in its name as principal or obligor. The BLM received a comment urging the BLM to analyze the bonding regime of the host State jurisdiction and decline further bond requirements where that State provides for bonding inclusive of Federal leases and wells. The BLM declines to adopt this proposal. Including such a provision in the BLM's rules would require the BLM to execute separate agreements between the BLM and the State to allow the BLM to access any funds available. Moreover, for such arrangements to work, the State bonding requirements must, at a minimum, cover all of the terms and conditions of a Federal lease, including the amount of uncollected royalties due to ONRR, plus the amount of money owed to the BLM, as the lessor, due to previous violations remaining outstanding. In the BLM's experience, these characteristics are uncommon. The BLM would be in favor of such an alternate bonding option if any State is interested in pursuing adequate arrangements, but the BLM cannot make or assume the existence of such commitments in this rulemaking.

A commenter stated that the BLM should modify this section because it is inconsistent with other sections and is confusing. For example, § 3104.10 states that, before the start of any surface disturbing activities, the lessee, operating rights owner, or operator must submit a bond, whereas this section states only that the operator must provide a bond in its name. The comment then stated that the BLM's primary concern should be that at least one person post the required financial assurance for a lease, and should leave it to the operator, lessee, and operating rights owner to determine among themselves who will provide the required bonding for a particular lease. The BLM concurs that its primary concern is that at least one person must post the required financial assurance for a lease and that the proposed changes to this section may cause confusion. Therefore, the BLM revised final § 3104.20 to be consistent with final § 3104.10, so that an operator, a lessee, or an owner of operating rights (sublessee) must be covered by a bond in its own name as principal or obligor. In order to be consistent with existing § 3171.9(a), the BLM added the following sentence to the final rule § 3104.20: ''The operator shall be covered by a bond in his/her own name as principal, or a bond in the name of the lessee or sublessee, provided that a consent of the surety, or the obligor in the case of a personal bond, to include the operator under the coverage of the bond is furnished to the BLM office maintaining the bond.''

One commenter expressed concern that the proposed rule did not consider related operators or subsidiaries operating under a parent company and could cause a parent company to be required to provide multiple bonds with significantly greater total bonding. The BLM disagrees. Under the existing and final regulations, the BLM allows for co-principals to submit a bond or to be added through bond riders. Bond riders can accompany the original bond or be filed subsequent to the acceptance of the bond. Therefore, the BLM is not making any changes to the final rule based on this comment.

A commenter urged the BLM to require that an individual lease bond be increased if it is to cover more than two wells, and, in determining the lease bond amount to be posted, that the BLM must take into account a number of variables including the well depth, the presence of other resources, the number of wells, the number of low-producing or inactive wells, the capability of any responsible party to carry out the reclamation, the anticipated condition of the well site, the extent of reclamation and remediation to be required, and compliance with the laws. The BLM declines to make any changes based on this comment, which, if accepted, would require the BLM to calculate each bond amount based on constantly changing conditions. That practice is unworkable given the number of bonds the BLM is required to maintain. The BLM already prescribes when a bond will be increased in § 3104.50.

Section 3104.30 Statewide Bonds

In the proposed rule, the BLM renamed the existing § 3104.3 due to the proposed elimination of nationwide bonds and proposed increase in the amount of statewide bonds to $500,000. The BLM received numerous comments suggesting a larger statewide bond amount if the bond: (a) covers more than seven wells; (b) is based on a number of variables; or (c) should be a set amount for each additional well. Another commenter recommended eliminating both nationwide and statewide bonds. The BLM declines to adopt these suggestions, which would require the BLM to calculate each bond amount based on constantly changing conditions; that practice is unworkable given the number of bonds the BLM is required to maintain. The regulations in § 3104.50 already specify when an increase might be required and provides the BLM with sufficient authority to review and ensure bond amounts are adequate.

Nationwide Bonds

The BLM proposed to remove nationwide bonding as an option due to the administrative burden they impose on the agency.

The BLM received comments supporting the removal of nationwide bonds. Those comments generally asserted that no nationwide option can fulfill the purposes of incentivizing operator reclamation and ensuring availability of adequate funds. Comments that opposed the removal of nationwide bonding stated there are benefits to continuing the nationwide tier for companies. Comments asserted that this change would deprive lessees and operators of a financial tool currently available to mitigate bonding costs by spreading them over a larger universe of leases and that the BLM's analysis that these bonds are administratively inefficient is not by itself a reason to remove nationwide bonds. Commenters pointed to language in a draft version of the IRA bill that included nationwide bonds, which Congress ultimately removed before the law was enacted.

The majority of the commenters who wanted the BLM to maintain nationwide bonds did not understand why the BLM considered nationwide bonds more difficult to manage and why the BLM proposed eliminating nationwide bonds. As stated in the proposed rule, for bond adequacy reviews, the BLM state office, which manages the nationwide bond, must coordinate with every field and state office with wells covered by this type of bond. The BLM administrative state office will usually contact between 4 (2 field offices and 2 state offices) and 40 (32 field offices and 8 state offices) offices and request these offices to conduct a bond adequacy review, which entails pulling the operator's well and inspection records. This is needed as the environmental and development situations may vary between offices. The administrative state office, while familiar with its field offices, would not be familiar with field offices in other administrative state offices. This will result in staff spending approximately 1 hour per office conducting the bond adequacy review and the administrative state office spending approximately 10 hours consolidating the reviews. With coordination required with between 4 and 40 offices, this would result in approximately $700 to $2,500 per bond adequacy review (assuming $50 hourly cost). Annually, this results in total costs of $33,740 to $120,500.

With this change, the BLM will no longer manage nationwide bonds and instead will have additional statewide bonds. The BLM estimates that the 243 nationwide bonds would become approximately 143 additional statewide bonds (see the Regulatory Impact Analysis for more information).[17] The BLM estimates that each administrative state office would be able to review one statewide bond using 10 hours of staff time ($500 per bond adequacy review). The administrative state office requires less time to compile the review from the field offices as there will be fewer field office reviews to compile, so any time needed by field offices within the state office would come out of the assumed 10 hours of staff time. This would result in an annual cost of $14,300, which is a reduction of $19,440 to $106,200 annually. Overall, the BLM sees significant administrative benefits with the elimination of nationwide bonds.

Additionally, the elimination of nationwide bonding in favor of the proposed increase in the amount of the statewide and lease bonds will allow the agency to focus on specific areas and fields to ensure the bonds are adequate to cover reclamation costs in the event an operator fails to complete proper plugging and abandonment. As of March 1, 2024, the BLM has identified 35 unplugged orphaned wells that were covered by nationwide bonds. The bonds covering these wells were insufficient, so the BLM must seek funds under the IIJA to plug these wells. Localized bonding to the individual or statewide level will allow the agency to ensure improved bonding reviews, reduces the administrative burden, and the BLM anticipates additional environmental benefits from this regulatory change. As discussed in the RIA, the BLM expects that the expedited timing for reclamation of orphaned wells from increased bonding could provide benefits related to wildlife, vegetation, soil erosion, climate change (reduced greenhouse gas emissions from unplugged orphaned wells), visual and aesthetic resources, ground water, and allowing the surface land to be utilized for other uses sooner (for example, for grazing purposes). The BLM cannot currently quantify these benefits using the information available to the BLM.

Finally, the BLM reviewed the concerns from some commenters that eliminating nationwide bonds would deprive lessees and operators of one financial tool for mitigating bonding costs. No additional data or support was provided beyond a statement that nationwide bonds mitigate bonding costs by spreading these costs over a larger number of leases. The BLM does not anticipate a large impact to lessees and operators from this change, given the other options available, such as reinstating CDs and LOCs. The RIA provides additional details on the impact of eliminating nationwide bonds.

Therefore, the BLM does not adopt the recommendation to reinstate nationwide bonds and is not making any further changes to this section. As stated in the proposed rule, the BLM will be able to better tailor statewide bond amounts to the local conditions and State-specific requirements when reviewing a bond for adequacy.

Section 3104.4 Unit Operator's Bond

The BLM proposed eliminating operator bonds because they are seldom used and because the bonds are obsolete. The BLM has been treating and managing these bonds like statewide bonds and eliminating them would create efficiencies in the program. The BLM received several comments that supported the elimination of unit operator bonds for the reasons the BLM provided. The BLM also received a comment stating the BLM should keep unit operator bonds without providing a reason why these should be kept. The final rule eliminates unit operator bonds.

Section 3104.40 Surface Owner Protection Bond

The BLM proposed adding this new surface owner protection bond section, which is cross-referenced to 43 CFR 3171.19, to provide for an additional type of acceptable bond that can be submitted when the operator is unable to reach a surface access agreement with the surface owner. The BLM requested comments on whether the BLM should increase the minimum bond amount. The BLM received numerous comments on § 3104.40.

The BLM received comments opposing the inclusion of this provision on the basis that it duplicates State law and should only apply to lands where the surface is private, or that the BLM also should address the interplay between existing § 3171.19(b)(2) that allows for an ''agreement'' with the surface owner in lieu of bonding, noting such an agreement does not necessarily require payment of ''compensatory damages'' as proposed in § 3104.40. Comments also stated the BLM should clarify that such bonds are not intended to cover reclamation, but rather only compensate a surface owner for inadvertent, limited purpose,

[17] The BLM reviewed its bonds and found many bonds tied to no existing liability or operations. The BLM expects to terminate the period of liability for many of the nationwide bonds without liability, which is why the 243 nationwide bonds would become approximately 143 statewide bonds.

''reasonable and foreseeable damages to crops and tangible improvements,'' as stated in the proposed rule.

Some comments supported the proposed $1,000 minimum bond amount, while others stated the minimum bond amount must be raised to at least $10,000 per well to support adequate remediation, plus an additional $2,000 per acre of disturbed land, and the impacts covered under the surface owner protection bond must be expanded beyond ''the reasonable and foreseeable damages to crops and tangible improvements.''

As stated in the proposed rule, the BLM promulgated the current requirements for surface owner protection bonds through Onshore Order 1 in 2007 and subsequently codified these requirements in 43 CFR subpart 3171. This bond is for the limited purpose of ensuring a private surface owner's crops and other tangible improvements are protected. In response to comments, the BLM has revised final paragraph (a) to remove the phrase ''to pay compensatory damages to the surface owner,'' to clarify the purpose of these bonds and added the phrase ''under 43 CFR 3171.19'' to encompass the situation where an agreement is reached with the surface owner. The BLM reviewed the surface owner protection bond amount and determined it appropriate for the narrow purposes of the bond. This bond covers ''the payment of such damages to the crops or tangible improvements (*i.e.,* agricultural, residential and commercial improvements, including improvements made by residential subdividers) of the entryman or owner.'' See 43 U.S.C. 299(a). The BLM has not made any changes to the minimum bond amount. Paragraph I provides a process to increase the bond if the surface owner objects to the sufficiency of the bond. This mechanism adequately addresses the unique cases where the minimum bond amount may need to be increased.

Finally, the BLM declines to incorporate a provision that requires the BLM to defer to State bonding requirements for surface owner protection bonds. First, not all States require a surface owner protection bond if the surface owner and Federal lessee cannot complete a surface use agreement for operations. In addition, a State's surface owner protection bond provisions may not provide the same coverage as required in the BLM's surface owner protection bond because the State bonds are required under the State's law and not under Federal law. See Wyoming Stat Ann. section 30–5–402, Colorado Code Regs. section 404–1–704, or New Mexico Stat. section 70–12–6. Therefore, the BLM declines to incorporate a provision that requires the BLM to defer to State bonding requirements for surface owner protection bonds.

Section 3104.50 Increased Amount of Bonds

Although the BLM did not propose any changes to the existing § 3104.5, it did receive the following comments and recommendations for the BLM to: (1) require an increase in the bond amount when the wells covered by the bond exceeds the number of wells that the BLM originally used to determine the new minimum bond amounts; (2) incorporate the BLM's bond adequacy review policy into the regulations; (3) require a bond review when an operator temporarily abandons or shuts-in a Federal well; (4) change or expand the risk factors described in paragraph (b); (5) state that an operator may satisfy a demand for an increased bond amount by providing another form of security; (6) state that any person aggrieved by a decision to increase bond amounts may seek review of a decision through State Director review and appeal to the IBLA; (7) remove ''uncollected royalties due,'' alleging that the bond amount should not include amounts demanded, payment of which is stayed pending appeals under 30 CFR part 1243; (8) explicitly state that operators do not need to provide a full liability bond; and (9) require bonds from record title and operating rights holders for unpaid royalty payments.

The MLA requires the Secretary to ensure that bonding is adequate, and, after review of the comments, the BLM has determined that no changes are needed to this section at this time. The BLM's proposed changes and additions in 43 CFR 3104.1 and existing regulations are sufficient to ensure compliance with the lease terms. Bonds given to the BLM are performance bonds to guarantee performance of the lease requirements. The performance bond protects the BLM, and ultimately the taxpayers, from financial loss should the operator fail to perform and comply with the regulations and laws governing lease operations. This financial loss includes unpaid royalty amounts; however, the BLM will first use the funds to address all outstanding plugging and reclamation costs. The BLM did not make any changes to the appeal language that already exists in the regulations and provides for both IBLA appeals in 43 CFR 3000.40 and State Director review when BLM staff recommend increased bond amounts pursuant to 43 CFR 3165.3(b).

In the proposed rule, the BLM requested comments on whether to require a bond adequacy review when a well is temporarily abandoned. The BLM received comments in support and opposition to this proposal. After reviewing the comments, the BLM has decided not to require a bond adequacy review for a change in well status, including temporary abandonment of a well. The BLM can review the adequacy of a bond at any time, and the new reporting and operational requirements for operators of temporarily abandoned wells will allow enhanced oversight of these wells. The BLM considers the discretionary authority to review a bond, combined with the new reporting and operational requirements, sufficient to effectively manage any risks to the environment associated with these types of wells without needing to require a bond adequacy review.

The BLM declines to change or expand the risk factors described in paragraph (b). The BLM considers the existing risk factors to provide an adequate basis for reviewing and identifying the appropriate bond amount. In addition, the BLM may consider additional risk factors on a case-by-case basis due to the language, which states, ''including, but not limited to,'' in the existing regulations and in the final rule.

Further, the BLM may need to require an entity to provide a full liability bond. It is the BLM's responsibility to take proactive measures to minimize the liability associated with high-risk operators. To mitigate the public's risk with a high-risk operator, the BLM may need to require a full liability bond on a case-by-case basis; therefore, the BLM declines to explicitly state that operators do not need to provide a full liability bond.

The BLM also declines to require bonds from record title and operating rights holders, in addition to operators, for unpaid royalty payments. The BLM's bonds required for operations cover both environmental liabilities and unpaid royalty payments. At one point, the BLM did require bonds from lessees; however, the BLM moved away from this practice in the 1980's due to the administrative burden related to requiring lessees and operators to maintain a bond. The BLM declines to require bonds from record title and operating rights holders, in addition to operators, for unpaid royalty payments.

While the BLM used the median number of wells to determine the new minimum bond amounts, an increase to the bond based solely on the number of wells is unwarranted. The BLM will capture the need for any bond increases

based on its bond adequacy reviews. It is the BLM's responsibility to take proactive measures to minimize the liability associated with high-risk operators, which may include full liability bonding in certain circumstances. The current BLM policy outlined in IM 2024–014, *Oil and Gas Bonds Adequacy Reviews,*[18] supplements the requirements in this section by directing reviews of existing Federal bond amounts and requesting increases to the bond amounts based on the potential risk or liability posed by the operators. As stated in the proposed rule, similar bond adequacy review policy has been in place for the past decade, and the BLM has periodically revised that policy to account for changing risk factors including, critically, the status of the well(s) and the operator's compliance history. The BLM declines to incorporate risk factors into the regulation in order to retain flexibility in bond reviews and allow it to adapt guidance more quickly to changing needs. If the BLM issues a decision requiring an increase in the bond amount, the regulations do not prohibit the operator from satisfying this by providing another form of security.

Section 3104.70 Default

To improve clarity, the BLM proposed to divide the existing § 3104.7 into three separate paragraphs and included language to address what happens in the event a party fails to comply with the requirements. The BLM received a comment objecting to paragraph (b)(2), stating that the paragraph effectuates the equivalent of suspension or debarment even if the BLM does not pursue that route—with its corresponding procedural protections—under paragraph (b)(3). The BLM is not proceeding with proposed paragraph (b)(2), which refers to preventing the bonded principal from acquiring additional Federal leases, at this time. The BLM prefers to continue to address this situation through policy, as an operator can still come back into compliance even after the bond is collected once all reclamation has been completed and all monies owed the U.S. have been paid.

Because the BLM is deleting the proposed paragraph (b)(2), proposed (b)(3) is now redesignated as (b)(2) in the final rule.

Section 3104.80 Termination of Period of Liability

The BLM did not propose any changes to existing § 3104.8 but did receive comments urging the BLM to revise the section to clarify that any new bond supersedes and replaces any prior bonds, and that the liability of the prior surety is terminated. The current language addresses this comment by stating the period of liability for a previous bond will terminate once the BLM receives a new bond meeting the regulatory requirements.

Section 3104.90 Unit Operator and Nationwide Bonds Held Prior to June 22, 2024

The BLM proposed this new section to address the elimination of unit operator and nationwide bonds and to provide the timeline by which entities must comply with the new bonding requirements. The BLM received a number of comments recommending that the BLM adjust the minimum bond amounts for inflation. The BLM has addressed comments directed at increasing bond amounts for inflation in § 3104.1.

A comment asked how the BLM plans to terminate the liability of sureties under unit operator and nationwide bonds that are being eliminated. After the final rules goes into effect, the BLM will send a notice to the principals maintaining the bond explaining the new requirement to replace their bond. Once an acceptable replacement bond is received, the period of liability will be terminated on the prior bond under § 3104.80. A replacement bond is not considered acceptable unless it also has an assumption of liability rider which assumes any outstanding liability accrued by the prior bond.

Multiple commenters requested that the BLM exempt existing operations and bond amounts as part of the final rule or provide more time to meet the increased bond amounts. The BLM declines to exempt existing bond amounts. The BLM, GAO, and OIG have concluded that the BLM's current bond amounts are inadequate to protect the Federal resources. If the BLM were to exempt those bonds covering existing operations, the problems identified by the GAO and the OIG would persist. The GAO, in report GAO–11–292, *Oil and Gas Bonds: BLM Needs a Comprehensive Strategy to Better Manage Potential Oil and Gas Well Liability,*[19] recommended that the BLM develop a strategy to increase the regulatory minimum bonding amounts over time and to more clearly define the conditions that warrant a bond increase beyond the minimum bond amounts. The BLM implemented these recommendations in policy; however, the GAO, in report GAO–19–615, *Oil and Gas: Bureau of Land Management Should Address Risks from Insufficient Bonds to Reclaim Wells,*[20] went on to recommend that the BLM should take steps to adjust bond levels, for all bonds, to more closely reflect expected reclamation costs. Reading these two reports, it is clear that the BLM should not exempt bonds covering existing operations. Similarly, the OIG, in Report No. OI–OG–12–0085–I, *BLM Oil and Gas Bonding Procedures,*[21] recommended that the BLM conduct and support bond adequacy reviews and bond increases periodically and do so before problems arise. If the BLM exempted the increased bond amounts for existing operations, the BLM would not be able to increase the bonds before problems arise for the existing operations. Further, increasing the bonds for all operators maintains a level playing field.

While the BLM declines to expand the phase-in periods overall, swapping them in final § 3104.1 to give individual bonds the longer phase-in periods will allow additional time for smaller operators with individual bonds to come into compliance. The holders of nationwide bonds are larger companies, which have increased staff and can more easily comply with the updated phase-in period to convert their nationwide bonds to statewide and/or individual bonds. The BLM updated the phase-in period in the final rule by requiring lessees and operators that currently use nationwide and unit bonds to come into compliance within 1 year of the effective date of the final rule. This phase-in period provides time for the BLM and its staff to process the increased and new bond amounts expected. The BLM has a total of 3,234 bonds: 975 individual or lease bonds, 1,987 statewide bonds, 19 collective (unit) bonds, and 253 nationwide bonds. Upon identifying that the majority of the bonds are statewide and individual bonds, the BLM determined that it made more sense to revise the phase-in period by requiring current nationwide bonds to be brought into compliance first and the others as follows:

- 1 year for nationwide and unit bonds,
- 2 years for statewide bonds, and
- 3 years for individual bonds.

Specifically, this phase-in period will provide individual lease bond holders—the majority of those affected by the provision of the rule, many of which are small businesses—more time to prepare

[18] *https://www.blm.gov/policy/im-2024-014.*

[19] *https://www.gao.gov/products/gao-11-292.*

[20] *https://www.gao.gov/products/gao-19-615.*

[21] *https://www.doioig.gov/sites/default/files/2021-migration/BLM%2520Oil%2520and%2520Gas%2520Bonding%2520Procedures.pdf.*

for compliance, and, likewise, will allow the BLM to prepare for the associated workload.

Section-by-Section Discussion for Changes to 43 CFR Subpart 3105

Communitization Agreements

Section 3105.21 Where Filed

The BLM proposed to remove the requirement in the existing § 3105.2–1 to file the agreement in triplicate and to specify the minimum contents for such an agreement. The BLM received comments on this section stating that the BLM should include a fixed filing fee for CAs. As previously stated, the BLM considered proposing new fixed filing fees for Federal CAs but ultimately declined to add a fee due to the public benefit of allowing Federal and State minerals that might otherwise be wasted to be developed.

A commenter stated that paragraph (c), which recommends that an application be submitted at least 90 days prior to first production, overlooks that CAs are commonly submitted only after production has been obtained, and are usually effective retroactively to the date of first production. The BLM's proposed language did consider this fact, which is why the proposed section says ''should'' instead of ''must.''

The final rule does not make further changes in response to these comments. The final rule did remove the acronym ''CA'' from the final regulatory text and replace it with ''communitization agreement'' for clarity and consistency.

Subsurface Storage of Oil and Gas

Section 3105.42 Purpose

The BLM revised the existing the existing § 3105.4–2 to clarify that gas storage agreement applications must include a bond. The BLM received a comment stating that such agreements should also be subject to a significant rental fee and bond. No additional changes are warranted in response to this comment because this section already covers the rental and bonding requirements. A fee is also required in § 3105.41.

Section-by-Section Discussion for Changes to 43 CFR Subpart 3106

The BLM proposed to add one section, remove two sections, and update the headings of each section to remove the outdated question and answer format that appears in the existing regulations. The BLM received a comment on this subpart stating the BLM should, as a matter of transparency, codify the policies and procedures that the authorized officer is required to follow with regard to approving and overseeing lease transfers. The BLM did not make any changes to this subpart based on this comment. The BLM has a handbook, H–3106–1, *Transfers by Assignment, Sublease, or Otherwise,* that provides the necessary guidance to the BLM to adjudicate these transfers. The public may obtain copies of this handbook, which is not currently available online, from any BLM state office.

Section 3106.10 Transfers, General

The BLM proposed splitting the existing § 3106.1 paragraph (a) to provide clarity, added a new paragraph (b) clarifying that the BLM will deny a transfer in certain situations, and added a new paragraph (c) limiting the transfer of operating rights. The BLM received a comment recommending the BLM address the impact of the severance of operating rights from record title interest. The BLM agrees with this comment. The BLM receives a multitude of transfers of operating rights that are unnecessary because those rights have never been severed from the record title. The final rule includes a new paragraph (b) to state that a record title assignment conveys both record title and operating rights unless operating rights have been previously severed. The remaining paragraphs are redesignated accordingly.

The BLM received comments on the proposed paragraph (b), which is final paragraph (c). The BLM added this paragraph to state an assignment of a separate zone, deposit, depth, formation, specific well, or of part of a legal subdivision, will be denied. One commenter supported this language, while another commenter stated that wellbore assignments are not ambiguous, because wellbores have API numbers that include bottom hole data and that are within approved drilling and spacing units specifying the acreage being drained by the wellbore. Wellbore rights are private agreements between private parties and need not be reported to the BLM. If the intent is to transfer a specific legal surface area and/or depth of the operating rights for a lease, a legal description of that area and depth is required.

A commenter stated that the language in the proposed paragraph (c), which is final paragraph (d), providing that operating rights interests may only be divided with respect to legal subdivisions is ill-advised, as it implicitly would preclude transfers of operating rights as to parts of legal subdivisions. The BLM disagrees with this comment. The paragraph must be read in conjunction with paragraph (a) that specifically states, ''Leases may be transferred by assignment or sublease as to all or part of the acreage in the lease or as to either a divided or undivided interest therein.'' The final rule adopts the proposed paragraph unchanged.

Section 3106.20 Qualifications of Assignees and Transferees

The BLM proposed revisions to the existing § 3106.2 to clarify that entities to whom record title or operating rights are being transferred must be qualified to hold a lease. The BLM received one comment on this section, requesting that the BLM revise the section to clarify that the new bonding requirements apply only to operators and not all lessees, assignees, and transferees. The BLM is not making any changes to the section in the final rule, because the bonding requirements may apply to any entity to whom an interest is being transferred and not just an operator.

Forms

Section 3106.41 Transfers of Record Title and of Operating Rights (Subleases)

The BLM proposed revising the existing § 3106.4–1 to require the use of an approved form to accomplish these transfers and to reduce the required number of copies the transferee must file with the BLM from three to two. The BLM received a comment on this section stating the BLM could not change from triplicate to duplicate filings as laid out in the proposed rule, because the required number of originally executed transfer forms is fixed at three by statute.

The BLM proposed this change in accordance with the Government Paperwork Elimination Act (GPEA), Public Law 105–227. Section 1707 of the GPEA specifically states, ''Electronic records submitted or maintained in accordance with procedures developed under this title, or electronic signatures or other forms of electronic authentication used in accordance with such procedures, must not be denied legal effect, validity, or enforceability because such records are in electronic form.'' After reviewing the comment and 30 U.S.C. 187a, the BLM determined that it should reinstate the triplicate filing until the BLM implements an electronic filing method. At that time, the BLM would only require one electronic filing per the GPEA. Therefore, the BLM reinstated the triplicate-filing requirement in this final section; however, the final rule also states the BLM will not require triplicate copies of the assignment or transfer when it is electronically submitted.

Section 3106.42 Transfers of Other Interests, Including Royalty Interests and Production Payments

The BLM proposed revising the existing § 3106.4–2 to require transfers of overriding royalty interest to be submitted on the BLM's approved form. The BLM received a comment asserting that the use of a BLM-approved form should not be required, since the transfer is not subject to BLM approval.

Although transfers of overriding royalty interest do not require the BLM's approval, an overriding royalty interest is an interest in a Federal oil and gas lease. By requiring such transfers to be on an approved BLM form, the transferee is certifying that they are qualified to hold the interest. The BLM adopts this section in the final rule without further changes.

Section 3106.60 Bond Requirements

The BLM proposed changes to existing § 3106.6 to clarify that an entity to whom an interest in the lease is being transferred has the requisite level of bonding. The BLM received a comment questioning why—if the previous lessee is only transferring a portion of its leases—the transferee must maintain the same level of bonding in cases where the previous entity had many more leases and other reasons for an increased bond amount. A commenter stated, for example, that the proposed rule provision would result in a new lessee, record title owner, or operating rights owner being required to maintain a full statewide bond when the assignor or transferor only transferred a portion of its Federal wells.

The BLM does not intend to require such results. Therefore, the final rule removes the phrase ''(including a statewide bond)'' as a statewide bond may not be necessary. When a lessee or operating rights owner maintains a bond for a lease, the BLM expects the transferee or assignee to maintain the same level of bonding for operations *on the transferred lease(s).* If previous lessees or operating rights owners held a statewide bond, the BLM will work with the new owner to identify the appropriate level of bonding for that lease.

The BLM received a comment recommending a revision to this provision to include the following language: ''to the same extent as the assignor's or transferor's bond, or to a greater amount if deemed necessary following a bond adequacy review.'' This addition was recommended to ensure the adequacy of bonds at the time of lease transfer. The commenter also requested that the BLM adopt additional requirements expressly requiring bond adequacy review at the time of transfer. The comment went on to state that such a rule should require the assignor or transferor to furnish the BLM with information on the number, type, and depth of all wells existing on the lease to be transferred, and should require the BLM to use this information—and any other relevant information—to assess whether the existing bond amount is adequate to ensure prompt and complete reclamation of all existing wells and any new wells that may be drilled by the assignee or transferee.

The BLM received a comment stating the BLM should harmonize this section with § 3104.20, which places the bonding obligation for a lease on the operator. The BLM primarily requires bonds from the operator instead of the lease interest owners (record title or operating rights owner). However, the BLM will require a bond from the lessees when the operator's bond is insufficient.

The BLM received a comment stating the BLM should include a requirement that the assignee's or transferee's bond be in place prior to the approval of the assignment or transfer. The BLM concurs and already requires the bond to be in place prior to approving the assignment or transfer and therefore sees no need for the change.

The BLM received a comment recommending that the BLM examine and certify the transferee's or assignee's financial viability before approving the transfer or assignment. This recommendation is not adopted in the final rulemaking as the BLM does not currently have the staff or expertise to perform this function.

Approval of Transfer or Assignment

Section 3106.72 Continuing Obligation of an Assignor or Transferor

The BLM proposed revising the existing § 3106.7–2 by removing the question-and-answer format in the title and clarifying the responsibilities of the assignee or transferee. The BLM received a comment recommending that the BLM change the language in paragraph (b) to delete the references to ''operating rights'' and make it clear that in the case of the transfer of any interest in a lease, the transferor must maintain financial assurances subsequent to the approval of the transfer and that all transferors should be required to maintain financial assurances for a predetermined suitable period after a transfer is approved.

The BLM is not making any changes to the final rule based on this comment, as the proposed regulations already address the concerns expressed by the commenter. Under § 3104.80, when the BLM terminates the ''period of liability'' on a bond, this action sets an exact date after which no new liability may accrue under that bond. In addition, the BLM prefers to keep the phrases ''assignment or transfer,'' so it is clear this section applies to both.

The BLM received a comment on paragraph (b) requesting clarification on the obligations described. The BLM has revised this paragraph in the final rule to clarify the obligations of the assignor or transferor once the BLM approves an assignment or transfer. The last sentence in paragraph (b) now states ''It also includes responsibility for plugging wells drilled and removing facilities installed or used before the effective date of the assignment or transfer.'' The BLM has added this sentence to provide a more comprehensive list of lease obligations; however, this is not a complete list. The assignor or transferor will continue to be responsible for other lease obligations, not limited to the items enumerated in § 3106.72(b).

Section 3106.73 Lease Account Status

The BLM proposed changes to the existing § 3106.7–3 to remove the passive voice and to clarify that the lease account must be in good standing with all royalties paid and lease obligations met. The BLM received a comment recommending a change to this provision by providing 60 days to allow a transferor whose account is delinquent to remedy the delinquency before the BLM rejects a transfer.

This recommendation is not adopted in the final rule. While some state offices suffer from a backlog of transfers, the BLM aims to adjudicate transfers within 60 days as required by the MLA. Adding the suggested language would prolong the time it takes the BLM to adjudicate an assignment or transfer. The denial of a transfer for this reason does not preclude the assignor or transferor from filing a new transfer with the appropriate filing fee after the lease account has been brought into good standing.

Section 3106.76 Obligations of Assignee or Transferee

The BLM proposed changes to the existing § 3106.7–6 to remove the question-and-answer format in the title and to update the language to be consistent with other changes being proposed. The BLM received a comment stating the regulation should also mandate the maintenance of financial assurances by the assignor of record and the transferor of operating rights for a

suitable amount of time after the transfer or assignment to ensure the continued protection of the Federal resource: (1) during the transition to a new lessee or operator; and (2) in the event of a latent issue that was not reasonably identified at the time of the transfer or assignment and for which the transferee or assignee refuses to accept responsibility.

No changes to the rule are necessary because an assignor or transferor remains liable for reclamation of wells during the period of liability. The period of liability is fixed under § 3104.80, when the BLM terminates the ''period of liability'' on a bond. After this date, which is an exact date, no new liability may accrue under the bond. Even if the liability is not apparent at the time the liability terminates, the assignor or transferor would remain liable.

Other Types of Transfers

Section 3106.81 Heirs and Devisees

The BLM proposed to split the existing § 3106.8–1 paragraph (a) into two separate paragraphs for clarity and included a reference to the new filing fee in paragraph (b). The BLM received a comment on the proposed § 3106.81 stating the proposed rule should be revised to state that the deceased party's rights will be assigned or transferred to the appropriate successors, which implies an affirmative act—whereas such a transfer in fact takes place by operation of law, and so the term ''assignment'' is misused in this context.

The BLM agrees and has revised the final paragraph (a) to update the phrase ''their rights will be assigned'' and inserts instead ''their rights would be assigned.'' The BLM also removed the word ''assignment'' from paragraph (b) and inserted ''transfer'' instead.

Section 3106.83 Corporate Mergers and Dissolution of Corporations, Partnerships, and Trusts

The BLM proposed to revise and update the title of the existing § 3106.8–3 and proposed splitting the existing paragraph into three to improve clarity. The BLM received a comment on § 3106.83 stating the requirement for a filing fee is noted only as to corporate mergers, whereas the fee schedule in the proposed rules under § 3000.120 of this title lists a fee that covers corporate merger and corporate dissolution.

The BLM agrees with this comment and in the final rule has updated the phrase in paragraph (d) from ''the processing fee for corporate merger'' to ''the processing fee for corporate merger or dissolution of corporation, partnership, or trust.''

9. Section-by-Section Discussion for Changes to 43 CFR Subpart 3107

Section 3107.10 Extension by Drilling

The proposed rule revised the existing § 3107.1 for clarity by splitting the first paragraph into two and adding a new paragraph to address directional or horizontal wells drilled off lease. One commenter stated language should be added to confirm that a lease is held by production from a directional or horizontal well.

The BLM has not made any changes based on this comment, because this application is already clear. As stated in § 3107.21, a ''lease will be extended so long as oil or gas is being produced in paying quantities.'' This language is clear that production on and attributed to any lease will be held by production from a directional or horizontal well. In addition, the BLM's Handbook H–3107–1, *Continuation, Extension, or Renewal of Leases,* states that ''for a lease to be continued by production, it must contain a well capable of producing oil and/or gas in paying quantities.'' The public may obtain copies of this handbook, which is not currently available online, from any BLM state office. This direction will include all leases that the directional or horizontal wells drilled into and producing from a Federal lease.

Production

Section 3107.22 Cessation of Production

The BLM proposed changes to the existing § 3107.2–2 in response to IBLA decisions holding that the section conflicted with the MLA. In this final rule, the section now states that a lease in its extended term expires 60 days after production ceases, and not after the lessee receives notice from the BLM. A comment expressed concern that this change may cause confusion and unintended consequences, as the operator of the well may not be the same as the record title owner and timely notice of a cessation of production may not be received to remedy the non-production and preserve the lease.

The BLM understands this concern; however, as explained in the preamble to the proposed rule, multiple IBLA cases have held that the existing regulation directly conflicts with section 17(i) of the MLA (30 U.S.C. 226(i)).

The BLM received a comment stating the last sentence in this paragraph should be amended to clarify this section. The BLM agrees and has revised the final rule by inserting the word ''paying'' prior to ''production''.

Extension of Leases Within Agreements

The BLM received a comment stating that the undesignated center heading that appeared immediately above proposed § 3107.31 is misleading and could easily be interpreted to mean the extension of agreement terms as opposed to the extension of leases within agreements.

The BLM agrees and the final rule adopts this recommendation and changes the heading from ''Extension for Terms of Agreements'' to ''Extension of Leases Within Agreements.''

Section 3107.31 Leases Committed to an Agreement

The BLM proposed to update the title of the existing § 3107.3–1, remove a reference to a provision that is no longer applicable, and add a new paragraph to address IBLA decisions pertaining to production in paying quantities. A comment stated the rule should clarify that unitized leases in an extended term cannot be further extended unless it is through production. The comment requested that the BLM clarify that the mere commitment of a lease to an agreement would not extend the Federal lease. No further changes are warranted to the final rule, because paragraph (a) already states ''*provided,* that there is production of oil or gas in paying quantities under the agreement prior to the expiration date of such lease.''

Finally, the BLM deleted the second ''for'' to clarify that both conditions must exist for the leases to continue to receive the extension. For the leases to receive this extension, (1) the leases must be committed to the authorized unit agreement and (2) the well must continue to be capable of production in leasing paying quantities (able to pay out the operating costs of the well).

Other Extension Types

A comment stated that the undesignated center heading that appeared immediately above proposed § 3107.71 is meaningless and should be changed. The final rule adopts this recommendation and changes the title from ''Other Types'' to ''Other Extension Types.''

10. Section-by-Section Discussion for Changes to 43 CFR Subpart 3108

Termination by Operation of Law and Reinstatement

Section 3108.21 Automatic Termination

The BLM proposed changes to the existing § 3108.2–1 to reflect policy changes by ONRR and to address IBLA decisions. The changes included adding a new paragraph (c) clarifying when the

automatic lease termination would apply. Some comments supported the addition of paragraph (c). Other comments stated the preamble to the proposed rule included a misleading example referencing lease suspensions that may require additional rentals when they are lifted that could result in conflict and confusion if left uncorrected.

That criticism is misplaced for the reasons discussed in the context of § 3103.42 in this preamble. To be clear, such a notice will depend on the timing of the lifting of the suspension in relation to the lease anniversary date. Consider the following hypothetical example: A lease is issued effective 7/1/90 with a five-year primary term, so it will expire on 6/30/95. The lessee paid the rental timely for the fourth lease year which ended on 6/30/94. The BLM granted a suspension of operations and production effective 4/1/94. The suspension was lifted effective 9/1/94. The revised expiration date of the lease is therefore 11/30/95, because the lease is extended an additional five months to account for the five months in which the suspension was in place. The rental paid for the 1993–94 lease year covers the remaining three-month period of the fourth lease year from 9/1/94 to 11/30/94. The prorated rental is to be requested from the lessee for the seven months from 12/1/94 through 6/30/95 (to bring the regular rental due date back to the lease anniversary date). No changes were made to the final rule based on this comment.

Section 3108.22 Reinstatement at Existing Rental and Royalty Rates: Class I Reinstatements

The BLM proposed changes to the existing § 3108.2–2 to reflect the fact that ONRR accepts rental payments through its online system. The BLM received a comment on paragraph (a)(2), asserting the change in this subparagraph would narrow the definition of ''reasonable diligence'' to include only rental payments made through ONRR's online system on or before the lease anniversary date and disregards ONRR's continuing practice of accepting non-electronic rental payments in some circumstances that would effectively eliminate reasonable diligence as grounds for Class I reinstatement. The BLM agrees and has revised the final rule by removing the phrase ''through its online rental payment system'' from paragraph (a)(2).

The BLM received a comment on paragraph (a)(3) stating that increasing the filing fee for Class I reinstatements from $90 to $1,260 is disproportionate to the administrative fee for Class II reinstatements which would remain at $500. As stated in the preamble to the proposed rule, the BLM considered moving the existing fee for Class II reinstatements to § 3000.120 for inclusion alongside the other fixed filing fees, increasing the fee to reflect the processing costs, and then adjusting the fee annually for inflation. However, the MLA, at 30 U.S.C. 188(e), specifically states for Class II lease reinstatements that ''[t]he lessee of a reinstated lease shall reimburse the Secretary for the administrative costs of reinstating the lease, but not to exceed $500.'' Accordingly, the BLM does not have the authority to increase this fee. The BLM also considered reducing the Class I reinstatement fee to $500 for parity with the Class II reinstatement fee and concluded that doing so would be insufficient to cover the BLM's administrative costs.

Section 3108.30 Cancellation

The BLM proposed revising the existing § 3108.3 to remove language in paragraph (a) that repeatedly called for the BLM to provide notice to the lessee prior to cancellation. The BLM received a comment stating that a provision should be added stating leases are subject to cancellation if the lessee is found not to be a ''qualified lessee'' or a ''responsible lessee.'' No changes have been made to the final rule as the BLM does not have the authority under the MLA to cancel a lease for these reasons. 30 U.S.C. 188. Further, the existing requirements at § 3102 would be applied prior to the issuance of a lease, and these requirements address this concern.

11. Section-by-Section Discussion for Changes to 43 CFR Subpart 3109

Section 3109.15 Compensatory Royalty Agreement or Lease

The BLM revised the existing § 3109.1–5 to align the terms of a lease issued under a ROW to those for a competitive lease. A commenter caught a technical error in subparagraph (c)(1) of the provisions of 43 CFR part 3100, where the BLM referenced a regulatory section number that does not exist (§ 3101.20). The BLM proposed and is removing the regulatory section numbers for headings that have no text associated with them, which included § 3101.2 in the previous regulations, and changed these sections to undesignated center headings. Therefore, the final rule makes a minor technical change to correct this error. The statement of ''except § 3101.20'' in paragraph (c)(1) has changed to ''except §§ 3101.21, 3101.22, 3101.23, 3101.24, and 3101.25.''

Sections 3109.21–3109.22 [Reserved]

In the final rule, the BLM removes the existing reserved §§ 3109.2–1 and 3109.2–2 as these sections do not need to be reserved. In the previous regulations, the BLM reserved § 3109.2–1 for the ''Authority to lease'' and § 3109.2–2 for the ''Area subject to lease.'' The BLM incorporated the authority to lease in 43 CFR 3100.3 and provides the area to lease in § 3109.20; therefore, the BLM no longer needs to reserve these sections in the final rule.

12. Section-by-Section Discussion for Changes to 43 CFR Part 3110

The final rule removes the existing 43 CFR part 3110 in its entirety. Multiple commenters expressed support for the elimination of 43 CFR 3110 to comply with Congress' repeal in the IRA of noncompetitive leasing for Federal onshore oil and gas minerals.

13. Section-by-Section Discussion for Changes to 43 CFR Part 3120

The BLM proposed to add two new sections and remove four sections from part 3120 to provide clarity and to ensure these provisions are consistent with other changes being made. The BLM received several comments on part 3120. Some comments specifically requested that the BLM not issue new leases in certain areas of the country. Some comments recommended additional paragraphs such as including denial criteria based on consideration of localized conditions and lands already subject to various types of adverse impacts. These comments are directed at the land use planning process, which is when the BLM evaluates whether lands should be open or not to leasing. Because these regulations govern the leasing and development process, these comments are outside the scope of this rulemaking.

Section 3120.11 Lands Available for Competitive Bidding

The BLM proposed changes to the existing § 3120.1–1 to reflect Congress' repeal of noncompetitive leasing in the IRA and revised the language in the introductory paragraph such that it more closely aligns with the Act.

Some comments argued that the proposed changes give the BLM more discretion for leasing than granted by the MLA; however, these arguments were made in reference to the timing of holding quarterly lease sales and not with respect to the BLM's discretion regarding what lands may be offered for lease. The introductory paragraph in

this section states, ''All lands eligible and available for leasing *may* be offered for competitive auction.'' The BLM changed the ''shall'' to ''may'' to clarify that the Secretary retains the discretion to decide, even after lands have been determined to be eligible and available, what lands will ultimately be offered for lease. Timing of any lease sales is addressed in final § 3120.12(a) which was modified to state, ''Each BLM state office will hold sales at least quarterly if eligible lands are available for competitive leasing.''

One commenter objected to the addition of the term ''eligible'' to this section. The BLM has not made any changes based on this comment as the proposed language merely reflects the language in the MLA at 30 U.S.C 226(a) and (b).

Another comment recommended that the BLM consider issuing a protective lease covering open Federal acreage located in an existing drilling block to provide a mechanism for a unit operator to develop its drilling block, including the unleased Federal minerals. The BLM cannot issue a protective lease, as proposed in the comment, under the MLA. The BLM may only issue a protective lease through a competitive lease sale based upon the law at 30 U.S.C. 226 and due to drainage of the Federal minerals (see 43 U.S.C. 1457; see also Attorney General's Opinion of April 2, 1941 (Vol. 40 Op. Atty. Gen. 41)). The BLM did not make any changes to the final rule based on this comment.

One commenter recommended removing ''including but not limited to'' from the introductory paragraph and inserting a new subparagraph (a) to state ''lands that have been identified as preferred leasing areas in a current land use plan as well as lands identified as exclusion areas in a current land use plan shall not be available for leasing.'' The BLM did not make any changes to this section of the final rule. The BLM already identifies the lands closed to leasing or open to leasing in its land use plans. In addition, the BLM does not identify ''preferred leasing areas'' within its land use plans. Since the BLM did identify that the lands must be available for leasing at the beginning of the statement, the BLM declines to make the changes proposed by the comment.

Section 3120.12 Requirements

The BLM proposed changes to the existing § 3120.1–2 to reflect current practices in holding lease sales via the internet, a new paragraph (c) to strengthen and revise the bidding process, the redesignation of paragraph (c) to (d), and inclusion of the new minimum bid amount. One comment recommended that the BLM add language clarifying that the BLM's discretion also applies to the timing of lease sales, and, specifically, that a sale need not be held if there are no eligible or available lands. The BLM has not made any changes to the final rule based on this comment, because paragraph (a) already states ''Each BLM state office will hold sales at least quarterly if eligible lands are available for competitive leasing.''

The BLM received a comment stating that paragraph (d) should state the minimum bid amount instead of referring to the BLM's website and changes to the bid amount should be made through the regulatory process. The final rule does not adopt this recommendation, as the minimum is stated in regulation: the BLM has moved the minimum bid amount required to the Fiscal Terms Table at § 3103.1, and all of the fiscal terms will be adjusted every 4 years through the regulatory process. Please note that the BLM will not adjust the minimum bonus bid until the amount set by the IRA becomes a minimum after August 16, 2032.

Section 3120.30 Nomination Process

The BLM requested comments on whether the formal nomination process should be retained in regulations and, if so, what changes to the formal nomination process should be made. The BLM received comments supporting the retention of the nomination process to promote leasing in areas with greater potential for fluid minerals to be produced. The BLM received comments stating the BLM should implement a single nominations process that combines elements of formal nominations and expressions of interest. These commenters contended that, by exercising its authority at the front end regarding what public lands it will consider for leasing, the BLM would reduce land speculation, save time and resources, and create greater certainty for all parties. The BLM received comments supporting the elimination of § 3120.30 stating this section is unclear, confusing, would only be used to limit lease areas, and that the BLM does not have the level of technical expertise required to adequately analyze lands for expected yields of oil and gas.

The final rule removes the formal nomination, existing §§ 3120.3 through 3120.3–7 and proposed §§ 3120.30 through 3120.33, which the BLM has never used and which generally increases the time and resources necessary to hold lease sales.

Expression of Interest

The BLM proposed adding a new section to address the process for EOIs, which previously had not been codified in regulation. The proposed rule also included the new filing fee requirement for EOIs in paragraph (d) as required by Congress in the IRA (see also the Fiscal Terms Table in final § 3103.1). The final rule redesignates the citation numbers throughout this section consistent with the removal of sections that pertained to the nomination process. The BLM received several comments on this section. Based on the BLM's review of the comments, the final rule splits the proposed § 3120.41 into two new sections. The first section describes the requirements for an EOI (proposed paragraphs (a) through (e), and (g)) and a new section is created for the preference criteria (proposed paragraph (f)).

Section 3120.31 Expression of Interest Process

The final rule renames the proposed section from ''Process'' to ''Expression of interest process'' and redesignates § 3120.31 from proposed § 3120.41 to final § 3120.31 as doing so will provide consistency with the previous regulations. This section contains paragraphs (a) through (d) of the proposed § 3120.41. Proposed paragraph (g) has been redesignated as paragraph (e).

One comment objected to the requirement that, for split estate lands under paragraph (b)(6), an EOI submitter must submit the private surface owner's name and address, even though there is no explicit and corresponding statutory requirement, and even though the information is often difficult and time consuming for submitters to obtain. The BLM has not made any changes to the regulation based on this comment. Under section 1835 of the Energy Policy Act of 2005 (43 U.S.C. 15801), Congress directed the Secretary of the Interior to review current policies and practices with respect to management of Federal subsurface oil and gas development activities and their effects on the privately owned surface. The Split Estate Report to Congress, submitted in December 2006, documents the findings resulting from consultation on the split estate issue with affected private surface owners, the oil and gas industry, and other interested parties. In the Report, the BLM identified in Issue 4 that ''surface owners would like to be contacted when the BLM is leasing Federal mineral estate underlying their property. Notification is requested when parcels are nominated and offered on a

competitive lease sale.'' As a result of work done to implement portions of the Energy Policy Act of 2005 relating to split estate lands, the BLM asked individuals submitting EOIs to provide the name of the private surface owner. This is outlined in BLM Handbook H–3120–1, *Competitive Leases.*[22] This information allows the BLM to notify the surface owner when the BLM initiates a lease sale that contains a parcel with minerals underlying the owner's surface. The BLM will require this information under paragraph (b)(6) to ensure the BLM provides adequate outreach to the private surface owners overlying Federal minerals.

The BLM received a number of comments on paragraph (d), which requires payment of the per acre fee required by Congress in the IRA. Some commenters recommended that the BLM should require the fee to be payable by the winning bidder instead of the individual that submitted the EOI or that the fee should be refunded if: (1) the lands are not included in a sale; (2) the individual that submitted the EOI does not obtain the parcel at the lease sale; or (3) the individual submitted an EOI covering lands already submitted on a prior EOI submittal. The BLM cannot make any of these changes as Congress did not provide the Secretary with this discretion in the IRA. That Act requires the assessment of a nonrefundable fee payable by any person submitting an EOI.

In proposed paragraph (e), the BLM included language allowing the BLM to include lands in a sale on its own initiative. The BLM received comments objecting to the provision, asserting it would allow the BLM to include lands it knows to be unattractive and does not account for the BLM's policy on unleased lands within CAs. That policy directs the BLM to offer such lands for competitive leasing as soon as possible, such that the lands should not be subject to nomination limitations or EOI criteria set forth in the proposed rule. After reviewing these comments, the BLM is removing proposed paragraph (e) from the final rule. That paragraph is unnecessary because § 3120.11(f) already gives the BLM the option to include lands selected by the authorized officer in a sale. The removal of paragraph (e) from this section clarifies that Bureau motions are not considered or counted as EOIs for purposes of calculating the percent of EOI acreage offered on oil and gas lease sales during the past year for renewable development under 43 U.S.C. 3006.

[22] *https://www.blm.gov/sites/blm.gov/files/uploads/Media_Library_BLM_Policy_h3120.pdf.*

As a final note, the BLM is clarifying that it only self-nominates lands to protect the Federal minerals and the public interest. The BLM calls self-nominated lands a Bureau motion. The BLM creates a Bureau motion to protect the Federal mineral estate from drainage or when there are unleased Federal minerals within an approved oil and gas agreement. The BLM tracks information on which parcels originate from an EOI or a Bureau motion within the BLM's National Fluid Lease Sale System. As of December 14, 2023, approximately 92 percent of the lands under review came from an EOI. The BLM identified that from the nominations received in calendar year 2023, the BLM has a total of 83,917.23 acres of pending lands under review with only 6,815.36 acres created from Bureau motions. The remaining 77,101.87 acres under review for future oil and gas leasing are created from EOIs.

The proposed paragraph (g) has been redesignated to paragraph (e) in the final rule and reflects the BLM's long-standing authority to determine which lands will ultimately be offered for sale. Therefore, the BLM makes no changes to this paragraph.

Section 3120.32 Expression of Interest Leasing Preference

The BLM revised the final rule by creating new § 3120.32, which had appeared in proposed § 3120.41(f). Both the proposed and final sections address the preference criteria that the BLM may use when determining whether, when, and in what order certain lands specified in an EOI should be processed and offered in a lease sale. Creating the new section required certain redesignations and reorganizations.

The BLM received many comments on this proposed section. Most of the comments were generally supportive of the preference criteria, though some commenters were opposed to the use of the criteria. Some comments that expressed support for the preference criteria requested additional criteria be considered or requested an expansion of the proposed criteria to include greater specificity. As discussed in Section III.B.2 and III.B.7 of this preamble, these comments recommended revising the criteria to better account for impacts on GHG emissions and climate change, environmental justice, the environment (often suggesting criteria for specific habitat, natural resource areas, land or aquatic conditions, species, or other factors), cultural and Tribal resources, specific recreational uses, and protected areas such as special conservation areas, parks, and wilderness areas.

Other comments opposed the consideration of any criteria by: (1) stating that adding preference criteria to preliminary leasing decisions will lead to delays, create uncertainty, and detract from the predictability of the process; (2) expressing concern that the application of the preference criteria would exclude lands that would be considered exploratory and that such exploratory actions benefit the public at large; and (3) stating that the proposed criteria process was duplicative of other statutory processes, such as those under the Endangered Species Act and FLPMA.

Many commenters also expressed views on the proposed process for considering criteria before offering parcels. Some comments stated the application of the criteria is not a transparent process or could be subjective. Some commenters expressed concern that the BLM lacks the technical expertise and resources needed to apply some of the preference criteria and sought clarifying language to ensure consistent consideration of the criteria by BLM offices, including identifying the sources of information that offices are expected to use. Specifically, for example, some comments stated that the proposed rule does not explain how the criteria will be used when conflicts between development and other uses occur or how the preferences will be weighted. Commenters offered varied approaches for how the criteria should be applied. For example, some comments stated that lands with a low preference should be excluded from leasing, and other commenters suggested that an EOI should represent compelling evidence of some potential for development. Additionally, some comments stated the preference criteria should not be applied to lands administered by another Federal agency.

After careful consideration of the comments received, the BLM is clarifying in the regulatory text that the BLM will consider the preference criteria as part of the scoping process for leasing. During the leasing process, the BLM will apply the criteria after the conclusion of the scoping process but before issuing a draft NEPA document for a lease sale. As such, the BLM has revised the last sentence in the introductory paragraph. The BLM is inserting the phrase ''In evaluating the lands to be offered, as part of the scoping process.''

Applying the preference criteria after scoping but before publication of the NEPA document allows the BLM to consider public comment on the environmental analysis for the lease sale

at the outset of the leasing process and to better manage its workload by directing its resources towards tracts that are most likely to be developed. Since BLM New Mexico's May 25, 2023, oil and gas lease sale, the BLM has been applying the preference criteria in this way through the BLM's policy IM 2023–007, *Evaluating Competitive Oil and Gas Lease Sale Parcels for Future Lease Sales.*[23] This process enables the BLM to conduct preference criteria review while the public and industry provides scoping comments, which the BLM will incorporate into its determination in the NEPA compliance documentation.

This procedural clarification also addresses many of the comments received. First, considering the criteria at the conclusion of the scoping process will allow the public to provide input that the BLM should consider when applying the criteria to the preliminary list of lands for a lease sale. Consistent with § 3120.42, the BLM will provide at least 30 calendar days for public comment on the preliminary parcel list as part of the scoping process. During this public scoping period, commenters can raise site-specific considerations that should be considered in selecting parcels. These could include many of the concerns commenters raised as potential additional criteria, such as the potential for development, environmental justice considerations, and other important uses or resources like watershed vitality. Public input also will help ensure that the BLM has the necessary data and information to evaluate the criteria. In response to public input, the BLM will be able to consider new information raised and announce its initial conclusions on the preference criteria in the draft NEPA document. Second, these steps provide transparency for the public to see how the BLM is considering the criteria on a case-by-case basis. For example, in some scenarios, it may allow the public to understand why low preference parcels are being offered for leasing or to recognize when there is a conflict between resources. This increased transparency and ability for public input are responsive to the comments received, including those that urged the BLM to add additional criteria that should be considered for the localized area and those that expressed concern that the process lacked clarity or transparency. At the same time, the BLM will more efficiently manage the process by applying the criteria before publishing the draft NEPA document. If the BLM applied the criteria to the parcels after publishing the draft NEPA document, the BLM may need to re-work or apply amendments and changes to both the draft NEPA documents and the competitive lease sale notice.

The BLM moved the statement ''at minimum'' to the end of the final sentence in § 3120.32. Consistent with the original wording in the proposed rule that directed the BLM to consider ''at a minimum'' the listed criteria, this language allows the BLM's authorized officer to consider other unenumerated criteria specific to local circumstances, including those raised in public comments. As such, the BLM declines to add, modify, or remove the preference criteria that were proposed. On a case-by-case basis, stakeholders and the public will be able to provide the BLM with pertinent information on the criteria or additional criteria to consider.

In addition, the BLM will not promulgate a specific weighting for the different criteria within § 3120.32 as the weighting will depend on the specific location and conditions in relation to local circumstances. Instead, the BLM will use the scoping process to inform the weighting for the different criteria. This will allow the BLM to incorporate public feedback on the parcels to be offered on the sale and ensure the BLM appropriately weighs the critical uses or resources. This will also allow the BLM to move forward with parcels that could be considered exploratory. The operator for the area can inform the BLM during the scoping period that it is interested in exploring for oil and gas in this area, which would provide for the BLM to weight the potential development criteria lower. The BLM disagrees that consideration of the preference criteria increases uncertainty or will lead to delays; rather, considering the criteria at the beginning of the leasing process will allow the BLM to more efficaciously select parcels for which to conduct environmental analysis and to offer at the lease sale. Ultimately, this will increase certainty and efficiency in the leasing process by decreasing the number of parcels offered that would not be leased, and relatedly, the number of parcels that are leased but never developed. By considering parcels that make the most sense to lease in terms of expected yields of oil and gas, the BLM is addressing concerns expressed in GAO's report, GAO 21–138, *Onshore Competitive and Noncompetitive Lease Revenues.*[24] The improved management of agency workflow will better use the BLM's time and resources and will not result in delay.

Additionally, rather than duplicating provisions under other statutes, the preference criteria will provide the BLM with an additional tool, consistent with the Secretary's broad discretion to lease lands for oil and gas development, to direct leasing and better avoid or manage conflicting uses of public lands at the outset of the leasing process. Because scoping is part of the NEPA process, application of the criteria will not be duplicative of the NEPA process.

The MLA vests the Secretary with broad discretion to decide, up until the time of lease issuance, whether particular parcels of Federal land ''may be leased'' for oil and gas development, see 30 U.S.C. 226(a). The MLA does not specify how and when this decision is to be made, and courts have consistently recognized the Secretary's discretion. *E.g., Udall* v. *Tallman,* 380 U.S. 1, 4 (1965) (''The [MLA] gave the Secretary of the Interior broad power to issue oil and gas leases on public lands'') *United States ex rel. McLennan* v. *Wilbur,* 283 U.S. 414, 419 (1931) (''there is ground for a plausible, if not conclusive, argument that so far as it relates to the leasing of oil lands [the MLA] goes no further than to empower the Secretary to execute leases which, exercising a reasonable discretion, he may think would promote the public welfare''). The preference criteria fit squarely within this discretion by aiding the BLM in directing leasing towards areas that are more likely to produce oil and gas and that are less likely to have conflicts with other uses.

Additionally, some comments sought clarification regarding the BLM's policy in IM 2023–007, *Evaluating Competitive Oil and Gas Lease Sale Parcels for Future Lease Sales.*[25] The BLM will continue to use this policy to guide the BLM's consideration of the preference criteria to evaluate parcels for competitive lease sales. The BLM's application of the IM as part of scoping has worked well for the 13 sales held in calendar year 2023, which resulted in over $158 million of total receipts.

During the BLM's review of the final rule, the BLM identified an error in the proposed rule for § 3120.32(c). The language in the proposed rule described the evaluation of ''the presence of historic properties, sacred sites, and other high value leasing lands, giving preference to lands that would not impair the cultural significance of such resources.'' In its guidance, however, the BLM described the evaluation of ''the presence of historic properties, sacred sites, or other high value cultural resources, giving preference to lands

[23] *https://www.blm.gov/policy/im-2023-007.*

[24] *https://www.gao.gov/products/gao-21-138.*

[25] *https://www.blm.gov/policy/im-2023-007.*

that do not contribute to the cultural significance of such resources.'' To avoid any implication that ''high value leasing lands'' were akin to historic properties, rather than an independent consideration, ''other high value leasing lands,'' the BLM has changed § 3120.32(c) to read ''other high value cultural resources.''

Finally, the BLM concurs that the other surface management agencies will have extensive knowledge on the relevant parcels and the BLM should give deference to those agencies. Therefore, the BLM is not changing the language in the regulation; however, the BLM's policy going forward will be for the BLM to provide its proposed application of the preference criteria to the surface management agency when requesting consent. The surface management agency can use the information provided by the BLM to determine if it will grant consent. For a parcel with the surface management agency's consent, the BLM may move forward to offer the parcels on a lease sale, irrespective of the preference the BLM would otherwise afford the parcels. As noted above, the Secretary retains full authority under the Mineral Leasing Act to determine which parcels are offered for sale.

Section 3120.33 Agency Inventory of Leasing

The BLM proposed this new § 3120.33 (redesignated from § 3120.42 in the proposed rule) to address the IRA's requirement (section 50265 [26]) that the Department offer leases for a certain amount of land for oil and gas development as a prerequisite to permitting any new solar or wind energy projects. Some of the comments supported the inclusion of this section, stating it is essential that the BLM take this leasing inventory to determine compliance with the IRA.

Some comments noted the new provision provides no calculation method and requested that the BLM consider codifying some of the calculation process set forth in IM 2023–006, *Implementation of section 50265 in the Inflation Reduction Act for Expressions of Interest for Oil and Gas Lease Sales.*[27] Others requested that the BLM should not rely upon IM 2023–006 for the calculation method. The BLM has not made any changes to this provision in the final rule and will continue to rely on the policy as set forth in IM 2023–006 to calculate the acreage.

Some comments suggested the rule be revised to require calculations to be performed on a quarterly basis, rather than leaving it unclear in the rule when to run such calculations. These comments asserted quarterly calculations would allow the BLM to determine the amount of public land acreage needed to be offered to allow wind and solar ROW permit issuance on an ongoing basis. Further, the comments suggested the BLM should only allow parcels receiving a low preference to be leased to allow wind or solar ROW issuance if additional acreage was needed based on the quarterly calculations. These calculations are only required on the day that the BLM would issue a wind or solar energy right-of-way; therefore, the BLM has not made any changes to the final rule based on this comment. The BLM will look at providing a mechanism for both the BLM and the public to generate reports and such calculations on demand.

Multiple comments stated the BLM should clarify in the final regulation that ''the 1-year period refers to the year before the wind or solar energy right-of-way is issued.'' The final rule adopts this recommendation and clarified that the 1-year period refers to the year before the BLM issues the wind or solar energy right-of-way in the final rule.

One comment stated the BLM should require that, before offering any parcel that receives a low preference designation for lease, the agency demonstrate that doing so is necessary to allow issuance of wind or solar ROW permits to comply with the IRA's provisions. The BLM declines to make any changes to the final rule based on this comment as it would needlessly restrict the BLM's discretion to determine which parcels to offer.

Notice of Competitive Lease Sale

The BLM did not receive comments on its proposal to redesignate the following two sections based on the other changes made in the proposed rule.

Section 3120.42 Posting Timeframes

The BLM proposed changes to the existing § 3120.4–2 to clarify its process for identifying parcels for a sale, the public's comment opportunities, and the timing of the BLM's posting of a notice prior to a sale.

Some comments recommended that the rule should: (1) require NEPA compliance documents to be made publicly available at the time the Notice of Competitive Lease Sale is posted; (2) specify that comment periods close at 11:59:59 p.m. (local time) on the last day of the comment period; (3) require key documents and information be translated into those languages that are the primary languages of communities impacted by the particular lease sale; (4) revise the rule to provide schedules for making data and information available to the public; and (5) require parcels to be in a format that both geographic information system (GIS) users and non-GIS users can easily understand. The BLM does not adopt these recommendations as these are provisions best addressed in a handbook as BLM policy guidance. The BLM will continue to allow the BLM state offices to manage the lease sales in a manner that works best for each office. The BLM already implements some of these recommendations and is committed to posting and making the NEPA compliance documents publicly available online. In addition, the BLM is continuing to develop the MLRS such that it will be capable of providing information spatially. Mapped views of the parcels are also displayed from the BLM's internet auction provider.

One commenter stated the key component of environmental justice is meaningful involvement of those most affected by a proposed project, agency action, or decision, while other commenters expressed the opinion that these changes are unwarranted and only serve to invite additional rounds of protests further delaying the leasing process. One commenter stated the BLM should issue the final NEPA documents prior to the lease sale to allow protests to be lodged before leases are sold. The BLM has not made any changes based on these comments. The BLM believes its codification of the opportunities for public comment on parcels to be included in a lease will allow for the meaningful involvement of those potentially most affected. Rather than providing for an additional round of protests, the changes to the regulation merely codify the BLM's current policy.

The final rule makes a minor technical change to include ''or appeals'' at the end of paragraph (a), which is consistent with the text of paragraph (b), and replaces the acronym ''NEPA'' with ''National Environmental Policy Act'' to assist readability of the final rule.

Competitive Auction

The final rule redesignated the following section numbers consistent with the removal of the nomination process from the final rule.

[26] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text.*

[27] *https://www.blm.gov/policy/im-2023-006.*

Section 3120.51 Competitive Auction

The BLM proposed changes to the existing § 3120.5–1 paragraph (a) to remove references to formal nominations, and to delete paragraph (c) for the same reason. The first sentence in paragraph (a) has been rewritten from ''Parcels shall be offered by oral or internet-based bidding'' to ''Parcels will be offered by competitive auction'' in the final rule. One commenter recommended that the BLM change its online auction format to allow parcels to remain open until bidding ceases, as under the current system the parcel is awarded to the highest bidder at the time the parcel times out.

The final rule does not adopt this recommendation. In the online bidding process, bidders are given ample time to review the parcels before a sale period opens for bidding. The bidding time is published, which will vary from sale to sale depending on the number of parcels offered, however the bid open and close time is clearly stated throughout the sale notice and in the auction. In the BLM's experience, most of the bidding occurs in the last few minutes of a parcel closing regardless of how long the bidding window is open. The BLM has found no data to support the assertion that the BLM will receive higher bids if the auction is allowed to run longer. Those bidding have a maximum amount they are willing to spend for a parcel and the amount of time allowed for bidding whether online or in person does not affect this.

Section 3120.52 Payments Required

The BLM proposed changes to the existing § 3120.5–2 to reflect changes enacted by Congress in the IRA and to be consistent with other changes made. The BLM received a comment recommending a change to paragraph (b) to clarify that the authorized officer can select a date other than the day of the sale for the payment.

The final rule adopts this recommendation and moves the phrase ''on the day of the sale for the parcel'' to earlier in the sentence to provide clarity. The final paragraph (b) now reads, ''Each winning bidder must submit, by the close of official business hours on the day of the sale for the parcel, or such other time as may be specified by the authorized officer.''

Some comments expressed the belief that the minimum bid was still too low or should be at least $20 per acre. The final rule does not adopt this recommendation. As previously explained, the minimum bid was changed to reflect the IRA, which requires $10 per acre.

The final rule makes a technical change to the cross reference for the minimum bonus bid in paragraph (b)(1) consistent with other changes in this rulemaking.

Section 3120.53 Award of Lease

The BLM proposed changes to the existing § 3120.5–3 to remove references to the noncompetitive lease process. The BLM received a comment recommending the BLM revise paragraph (b) to state that a ''lease will be awarded to the highest responsible and qualified bidder unless contrary to the public interest.'' The final rule does not adopt this recommendation. The BLM has historically used a public interest requirement in its oil and gas agreements, which require a drilling of a well into the target formation for a CA or drilling of the obligation well for an exploratory unit agreement. Adding a public interest requirement to this section may cause confusion related to the use of this same phrase with agreements. The Secretary still has the discretion to consider the public interest in the ultimate decision of which lands to lease.

A commenter stated that paragraph (d) should be revised to state that the lease will not be issued until all appeals are resolved in addition to the resolution of all protests. The final rule does not adopt this recommendation, because the MLA requires all leases to be issued within 60 days following the payment of any remaining bonus bid and rentals for the first year.

Comments opposing the inclusion of paragraph (e) stated that the BLM should not reject a lease offer without the bidder's consent if the protest is not timely resolved. In this section of the regulations, the BLM may reject a bid if the BLM cannot issue the lease within 60 days as required under 30 U.S.C. 226(b)(1)(A). However, the BLM concurs that it should not reject the bid without the successful bidder confirming that it would prefer its bid to be rejected rather than waiting longer than 60-days for the lease to be issued. Based on this comment, the BLM has revised this section in the final rule by inserting the phrase ''with the consent of the bidder'' to clarify the BLM's intent.

14. Section-by-Section Discussion for Changes to 43 CFR Subpart 3137

The final rule does not make any revisions to the section designations or the headings that appeared in the proposed 43 CFR subpart 3137 regulations. The BLM did not receive any comments on these sections and adopts the proposed changes in the final rule.

15. Section-by-Section Discussion for Changes to 43 CFR Subpart 3138

The final rule does not make any revisions to the section designations or the headings from the proposed rule for the 43 CFR subpart 3138 regulations. The BLM did not receive any comments on these sections and adopts the proposed changes in the final rule.

16. Section-by-Section Discussion for Changes to 43 CFR Subpart 3140

The final rule does not make any revisions to the section headings in the existing 43 CFR subpart 3140 regulations. It does redesignate the sections to make them conform to current Office of the Federal Register (OFR) Document Drafting Handbook requirements.

Section 3140.13 Exploration Plans

The BLM identified that paragraph (c) contained a technical error and referenced an outdated section number of the regulations. The final rule corrects the reference to § 3140.23. The BLM did not receive any comments on § 3140.13 and did not make any other changes to the final rule.

Section 3140.14 Other Provisions

The BLM proposed changes to the existing § 3140.1–4 to update the rental and royalty provisions. The BLM identified that existing paragraph (a) contained a technical error and referenced an outdated section of the regulations. The final rule corrects the references to 43 CFR 3101.21 and 3101.22. One comment suggested that the current rule set out the actual required rental amounts to ensure the regulations serve as an orderly source for basic information. The BLM revised paragraph (b) to provide this reference.

The BLM received a comment on paragraph (d) referencing the unitization provisions in 43 CFR part 3180. The commenter recommended that the BLM revise the final rule to provide that a lease, or part of a leasehold, having been made part of a unitized area will not be sufficient to extend the primary term of the entire leasehold and if the lessee fails to take actions to extend those portions of the lease outside of the unitized portion of the leased lands, the lease should expire as to those excluded lands. The BLM reviewed this comment and determined the suggested revision is unnecessary as it is already addressed inf 43 CFR 3107.32.

17. Section-by-Section Discussion for Changes to 43 CFR Subpart 3141

The final rule does not make any revisions to section headings in the existing 43 CFR subpart 3141

regulations. It does redesignate the sections to make them conform to current OFR Document Drafting Handbook requirements.

Section 3141.8 Other Applicable Regulations

The BLM did not receive any comments on the existing § 3141.0–8. However, when the BLM reviewed the regulations during drafting of the final rule, it identified that it needed to update § 3141.8(a)(1)(ii) to reflect the provisions in § 3140.14(a). Under 30 U.S.C. 226(b)(2)(A)(iv), ''no lease issued under this paragraph shall be included in any chargeability limitation associated with oil and gas leases.'' Therefore, the BLM updated this paragraph after reviewing the law and the applicable **Federal Register** notices that established these two sections of the regulations. See 48 FR 7420 (February 18, 1983), 47 FR 25720 (June 14, 1982), 47 FR 8734 (March 1, 1982), and 47 FR 22474 (May 24, 1982). Paragraph (ii) contained a technical error as it incorrectly applied the chargeable acreage and acreage limitations to combined hydrocarbon leases. Therefore, the BLM revises § 3141.8(a)(1)(ii) in the final rule to provide that all of 43 CFR 3101 applies to combined hydrocarbon leases, except for the chargeability limitation associated with oil and gas leases.

In addition, the BLM corrected an incorrect cross reference in proposed § 3141.8(a)(1)(iv). This final rule changes the cross references in this section to §§ 3103.21, and 3103.31(a), (b), and (c).

In addition, the BLM updated the cross reference in § 3141.8(a)(1)(vii) because the final rule adds another paragraph, which changed the reference to § 3106.10(j).

Finally, the BLM updated the cross reference in § 3141.8(c)(1)(ii) because the proposed rule referenced an incorrect citation. The final rule will correct the references to §§ 3103.31 and 3103.32 instead of § 3103.30.

Section 3141.53 Royalties and Rentals

The BLM proposed changes to the existing § 3141.5–3 mainly to address changes required by Congress in the IRA. One commenter objected to royalty rate reductions for tar sand leases and recommended that the royalty rate not be reduced. The BLM understands the concern but cannot make this change as the reduction is allowed by the statute, see 30 U.S.C. 226(b)(2)(D).

Section 3141.63 Conduct of Sales

The BLM proposed eliminating paragraph (a) and updating (b) to provide a consistent approach for combined hydrocarbon leases and tar sand leases. One commenter objected to the noncompetitive leasing of additional lands for tar sand development. The BLM can no longer issue noncompetitive tar sand leases after the passage of the IRA [28] and does not include a provision in the final rule that provides for noncompetitive leasing; therefore, the BLM did not make any changes to the final rule based upon this comment.

18. Section-by-Section Discussion for Changes to 43 CFR Subpart 3142

The final rule does not make any revisions to the numbering or section headings from the proposed rule for the 43 CFR 3142 regulations. The BLM did not receive any comments on these sections and adopts the proposed changes in the final rule.

19. Section-by-Section Discussion for Changes to 43 CFR Subpart 3151

The final rule does not revise the proposed section designations or their headings in the 43 CFR subpart 3151 regulations.

Section 3151.30 Collection and Submission of Data

The BLM proposed revising the existing § 3151.30 to require a permittee to submit to the BLM all data and information collected under a geophysical exploration permit. A commenter expressed concern related to the potential release of geophysical exploration data to competitors through a Freedom of Information Act (FOIA) request. The BLM understands the concern that geologic data be kept confidential. Geological and geophysical data is exempt from release under FOIA pursuant to exemption 9, 5 U.S.C. 552(b)(9). Although exemption 9 under FOIA would allow this information to be exempt from release, the BLM also updated the final regulations to ensure it is clear that the BLM would not release this information to the public by including new paragraph (b), which adds the statement that all information submitted under this section ''is presumptively confidential business information.''

The commenter also stated that the BLM provided no basis for why the BLM needs this information, how it will be used, or with whom it will be shared. Such data will support the BLM's review and analysis of oil and gas agreement applications and oil and gas leasing decisions. The BLM will use this data to inform an area's oil and gas development potential. In addition, the geophysical exploration data will allow the BLM to make better decisions related to an exploratory unit agreement's boundary by ensuring that the unit area encompasses only those lands necessary for the proper development of the unitized resources. This information is exempt from release to the public under exemption 9 of FOIA, and the BLM will respect and maintain the confidentiality of the information.

20. Section-by-Section Discussion for Changes to 43 CFR Subpart 3160

The final rule does not make any revisions to the section designations or their headings in the existing 43 CFR subpart 3160 regulations.

Section 3160.0–5 Definitions

The BLM proposed revising existing definitions and added some new definitions. The final rule does not make any changes from the proposed rule for the definitions within the existing § 3160.0–5.

One commenter requested that the BLM defer to the definitions and analysis from State regulatory bodies for what constitutes temporarily abandoned and shut-in wells, because the proposed regulations do not match State standards and could lead to inconsistency and confusion, particularly on Federal wells that are communitized with State or fee leases. The BLM understands the concern; however, the BLM declines to adopt this change because the BLM's definitions are in keeping with its statutory authority. For example, 30 U.S.C. 226(i) states that a lease will not expire if it contains a well capable of producing oil or gas in paying quantities. The BLM's proposed definition reflects this statutory requirement by defining ''temporary abandoned well'' as ''a nonoperational well that is not physically or mechanically capable of production or injection without additional equipment or without servicing the well, but that may have future beneficial use.'' Thus, a temporarily abandoned well would not be considered capable of production. This differs from, for example, the Wyoming Oil and Gas Conservation Commission's definition for ''temporarily abandoned'' that would not comport with the statutory framework. That definition is ''a well in which the completion interval has been isolated from the wellbore above and the surface. The completion interval may be isolated by a retainer, bridge

[28] Inflation Reduction Act, Section 50262(e), *https://www.congress.gov/bill/117th-congress/house-bill/5376/text.*

plug, cement plug, tubing and packer with tubing plug, or any combination thereof.'' In addition, each State has different definitions for temporarily abandoned wells and shut-in wells. If the BLM deferred to State regulatory body definitions, the BLM would have internal inconsistencies related to well status definitions, which would result in inconsistent regulatory and policy implementation based on different definitions for temporarily abandoned wells and shut-in wells. Therefore, the BLM declines to adopt this recommendation.

A commenter requested that the rule provide a definition of ''temporarily abandoned well'' that includes a reference to a well that may have ''future beneficial use'' and provided a recommended definition of ''a well that has the potential to produce oil and natural gas in the future as deemed by a reasonable operator including after recompletion, workover, and other maintenance activities. It also includes wells that have potential for geothermal, carbon management, scientific applications, technological advances, or other exploration and production related activities.'' The BLM declines to provide the definition as proposed by the commenter in the final rule and notes that reuse or conversion of wells for other purposes is not the subject of this rule. Moreover, the commenter's proposed definition varies significantly from the BLM's current policy regarding whether a well is producing or is abandoned, as found in Attachment 4 of IM 2020–006, *Idled Well Reviews and Data Entry,*[29] which provides guidance to BLM personnel about whether they should take any action with respect to wells that are not currently producing in an effort to prevent such wells from becoming orphan wells. Attachment 4 states the BLM ''will consider a well to have future beneficial use if the operator will be able to use the well to generate royalties in lease paying quantities or will support the operator's efforts to generate royalties from other wells on the lease.'' Therefore, the BLM did not make any changes to the definitions based upon this comment.

Another commenter recommended that the BLM define idled well, orphaned well, and inactive wells. The BLM declines to define these terms because the BLM does not use these in the regulations. In addition, the law defines both idled wells at 42 U.S.C. 15907(a)(2) and orphaned wells at 42 U.S.C. 15907(a)(5).

Finally, a comment recommended updating the definition of maximum ultimate economic recovery to include references to the BLM's responsibilities under FLPMA. The BLM declines to update this definition at this time. The BLM uses this definition in parts 3160 and 3170 to identify the maximum amount of oil and gas that could be produced from the reservoir using existing technology. This definition already is used in conjunction with the FLPMA requirements in part 3160 (see 43 CFR 3162.1(a)). In part 3170, the term is used to determine if a variance is appropriate (see 43 CFR 3173.14(b)(4)) and in relation to off-lease measurement. Based upon a review of the usage of the maximum ultimate economic recovery in the regulations, the BLM determined that it was unnecessary to include references to the BLM's responsibilities under FLPMA as part of this definition.

21. Section-by-Section Discussion for Changes to 43 CFR Subpart 3162

The final rule does not make any revisions to the section designations or their headings in the existing 43 CFR 3162 regulations.

Section 3162.3–4 Well Abandonment

The BLM received many comments both in support of and expressing concern on the proposed revision of the requirements for operators to monitor, track, and report on shut-in and temporarily abandoned wells. After reviewing the comments, the BLM has made the following changes:

(1) Reorganized paragraphs (c) and (d) pertaining to temporarily abandoned wells to ensure they are easy to read;

(2) Matched the plugging requirement between shut-in and temporarily abandoned wells in paragraph (d);

(3) Clarified in paragraph (e) that an onshore operator will only need to report a well as shut-in if the well will be shut-in for 90 consecutive days; and

(4) Required mechanical integrity tests every 3 years after a well is shut-in or temporarily abandoned in paragraph (f).

For paragraph (b), one commenter objected to the requirement that ''[a]ll costs over and above the normal plugging and abandonment expense will be paid by the party accepting the water well.'' The commenter recommended that the BLM revise this paragraph to allow the operator of the well, the State, a grazing association, or any other non-Federal entity to pay the additional costs if a well is being conditioned into a water supply source. The BLM did not propose any changes to this paragraph and disagrees with the commenter. If the operator does not need the water well and it is not supporting on-lease activity, the BLM cannot require the operator to cover any additional costs related to setting up the well as a water well. If the operator of the well, the State, a grazing association, or any other non-Federal entity agrees to pay the additional costs for a well to be conditioned into a water supply source, the BLM will work with the funding entity and the party accepting the water well. In general, this would be a private arrangement between the party accepting the water well and the other entity. The BLM did not make any changes to the final rule based upon this comment.

In reviewing the final rule for clarity, the BLM identified that the requirements for temporarily abandoned wells were included in a single paragraph at paragraph (c) in the proposed rule and were difficult to follow. Therefore, the BLM split paragraph (c) into two paragraphs (c) and (d) in the final rule and re-structured paragraph (d) to match the format for the requirements for shut-in wells in the final rule with the format for the requirements for temporarily abandoned wells.

Although a few commenters expressed support for the 4-year requirement to plug temporarily abandoned wells, one commenter recommended a 2-year requirement, and other commenters expressed concerns that the 4 years proposed was too short. The BLM reviewed these comments and identified that there are legitimate reasons why a well may need to remain temporarily abandoned for longer than 4 years. For example, an operator may be looking at converting a field for enhanced recovery. Until the operator has constructed the infrastructure to support the operations, multiple wells may need to be temporarily abandoned since they will not be used until the operator starts injections. Based upon this scenario and other considerations expressed in the comments, the BLM updated the final rule in paragraph (d) (paragraph (c) in the proposed rule) to match the requirements for shut-in wells and temporarily abandoned wells for final abandonment. The final rule now provides an option to ''provide the authorized officer with a detailed plan and timeline for future beneficial use of the well. If the authorized officer determines that there is a legitimate future beneficial use for the well, the officer may allow the operator to delay permanent abandonment by an additional 1 year. The authorized officer may grant additional delays in 1-year increments, provided that the operator confirms the future beneficial use of the well and is making verifiable progress

[29] *https://www.blm.gov/policy/im-2020-006.*

on returning the well to a beneficial use.'' This language matches the requirements for shut-in wells.

In revising the regulation to allow a well to be temporarily abandoned for longer than 4 years, the BLM determined that it needed to ensure that these nonoperational wells maintain their mechanical integrity. Therefore, the BLM added paragraph (f) to require mechanical integrity tests every 3 years, after the first mechanical integrity test is done. This section states, ''All wells that are temporarily abandoned or shut-in must have mechanical integrity verified as required in (d)(1) and (e)(2) and must ensure that mechanical integrity is verified every 3 years thereafter. The operator must submit the results of each verification of mechanical integrity to the Authorized Officer within 30 days of the mechanical integrity test.''

One commenter requested that a provision be added to the regulations that allows recreational access to the reclaimed locations. Once the lands have been reclaimed and the BLM has accepted an abandonment notice, the public may use the lands for recreation, provided the applicable RMP allows for such use.

One commenter expressed concerns related to the proposed rule's requirement that ''no well may be temporarily abandoned for more than 30 days without the prior approval of the authorized officer.'' The commenter requested that the BLM extend the temporary abandonment period for which a notice and prior approval is required from 30 days to 90 days. The thirty-day period has been in place since 1988, and the BLM is unaware of evidence showing that it or operators have experienced hardship from the period. Therefore, the BLM kept the current requirement of 30 days for notice and prior approval.

The BLM requested comments on whether to require a bond adequacy review when a well is temporarily abandoned. The BLM received comments in support and opposition to this proposal. After reviewing the comments, the BLM has decided not to require a bond adequacy review for a change in well status, including temporary abandonment of a well. The BLM can review the adequacy of a bond at any time, and the new reporting and operational requirements for operators of temporarily abandoned wells will allow enhanced oversight of these wells. The BLM considers the discretionary authority to review a bond, combined with the new reporting and operational requirements, sufficient to effectively manage any risks to the environment associated with these types of wells without needing to require a bond adequacy review.

Commenters expressed concerns that the extra administrative requirements related to temporarily abandoned and shut-in wells will become overly burdensome for the BLM to administer and will result in contradictory guidance and confusion for operators balancing between State and Federal regulations. One commenter also mentioned the number of orphaned wells that have been identified on Federal lands. Another commenter suggested the BLM should not require operators to report a well status change to the BLM because ONRR requires operators to report on ONRR Form-4054 (''OGOR'') the well status (Well Status codes 12 (OSI) and 13 (GSI)) beginning with the last month of drilling and continuing until the operator abandons the well. Another commenter stated that the BLM should accept all sundry notices for temporarily abandoned or shut-in wells as prima facia rationale and timing parameters for these nonoperational wells. After reviewing the comments, the BLM identified that paragraph (d)(1) in the proposed rule required operators to report whenever a well is shut-in. The BLM did not intend for an operator to report each time a well is shut-in. Instead, the BLM need only be notified if the well would be shut-in for 90 consecutive days. Therefore, the BLM revised this section to state, ''Notify the authorized officer of the well's shut-in status, if the well will be shut-in for 90 or more consecutive days, and provide the date the well was shut-in within 90 days of well shut-in.'' As for the administrative burden concerns, the BLM has reduced the operator's administrative burden with this change since the operator would not need to submit a notice for each shut-in well. Instead, the operator will only submit a notice for each well shut-in for 90 or more consecutive days. The final rule will also reduce the BLM's burden as the BLM can use the notifications to update well status instead of requiring the BLM to inspect wells or review ONRR or State agency data on well status. The BLM will review notification of shut-in or temporarily abandoned status to determine if the rationale for shutting-in or temporarily abandoning the well are supported by the information provided in the notice. The BLM will accept the sundry notice and update the well status in its system; however, the BLM will not provide a guarantee that it will consider each sundry notice as prima facia rationale for the status change. The BLM has a responsibility to the American public to ensure that unplugged non-operational wells are still necessary to support lease operations. If the unplugged non-operational well will not support future lease production, then the BLM will request that the operator plug and abandon the well.

Finally, the BLM reorganized this section in the final rule. The BLM removed the requirements for temporarily abandoned wells from paragraph (d) and left the reclamation requirements for all wells permanently abandoned within paragraph (c). The BLM reorganized paragraph (d) for temporarily abandoned wells to add subparagraphs and ensure the language in the final rule was clear. The BLM redesignated the section for shut-in wells to paragraph (e). The BLM also added paragraph (f) to cover the requirements for mechanical integrity tests. The BLM makes these changes in the final rule to more clearly inform the regulated community of the requirements.

22. Section-by-Section Discussion for Changes to 43 CFR Subpart 3164

The final rule does not make any revisions to the section designations or their headings in the existing 43 CFR subpart 3164 regulations.

Section 3164.1 Onshore Oil and Gas Orders

The BLM changed the existing paragraph (b) to clarify that there are no Onshore Oil and Gas Orders currently in effect. Since the BLM codified the Onshore Oil and Gas Orders in 43 CFR part 3170,[30] the BLM wants to ensure the regulated community is aware that they must follow 43 CFR subpart 3171. Therefore, the BLM removes the references to the Onshore Orders in this section. All of the Onshore Oil and Gas Orders are now codified in 43 CFR subparts 3171, 3172, 3176, and 3177. See 88 FR 39514 (June 16, 2023).

23. Section-by-Section Discussion for Changes to 43 CFR Subpart 3165

The proposed rule revised the heading for 43 CFR 3165.1 from ''Relief from operating and producing requirements'' to ''Relief from operating and/or producing requirements.'' The BLM did not receive any comments on this change and did not make any other changes in the final rule.

[30] Onshore Oil and Gas Operations; Federal and Indian Oil and Gas Leases; Codification of Onshore Orders 1, 2, 6, and 7 (88 FR 39514, June 16, 2023). *https://www.federalregister.gov/documents/2023/06/16/2023-11742/onshore-oil-and-gas-operations-federal-and-indian-oil-and-gas-leases-codification-of-onshore-orders.*

Section 3165.1 Relief From Operating and/or Producing Requirements

The BLM revised the existing § 3165.1 to encourage diligent development of leased lands and to ensure that any lease suspensions are justified and have a clearly stated end date. The BLM received many comments on the proposed rule related to changes to oil and gas lease suspensions. The final rule revises paragraph (c) to add the word ''only'' before ''cites'' and replace the acronym ''APD'' with ''application for permit to drill.''

A commenter expressed concerns regarding the proposed changes in light of the BLM's own delays in processing APDs and lease suspensions and with agency policy against ''premature suspensions.'' The commenter asked the BLM to clarify its intent so that lessees can clearly understand the appropriate time by which they should submit any requests for suspensions. The BLM agrees and drafted paragraph (c) to specify the timeframe for a submission of an APD such that a lessee could seek a suspension based upon a pending APD. The BLM does not believe any other changes are necessary.

For paragraphs (a) and (b), one commenter recommended that the final rule should require the ''full statement'' to include a showing of leaseholder diligence, 2and absent a showing of diligence, the BLM would be required to deny the request for relief. The BLM's existing policy in Manual Section 3160–10, *Suspension of Operations and/or Production,*[31] already suggests the BLM ensures that a lessee is diligently developing its lease prior to granting a suspension. The manual states, ''Suspension of operations may be directed or consented to by the authorized officer in cases where a lessee is prevented from operating on the lease, *despite the exercise of care and diligence,* by reason of force majeure, that is, by matters beyond the reasonable control of the lessee.'' (*Emphasis added*). The manual has similar guidance for suspensions of production. In addition, the BLM also not infrequently grants suspensions when litigation precludes development on an undeveloped lease. In these cases, the lessee could not provide a showing of leaseholder diligence when requesting a lease suspension because the BLM recently issued the lease. Therefore, the BLM did not make any changes in the final rule further specifying requirements for the full statement.

One commenter stated that the BLM should not add paragraph (c) into the final regulations, but instead leave the substance of the paragraph in guidance. Additionally, multiple commenters claimed that the authorized officer should have flexibility to approve a lease suspension in spite of the timing of the APD, if the officer believes it would be appropriate given the circumstances. The commenter then stated that the BLM should not push the operator towards diligent development, as the submission of an APD is a business decision based on markets, investment capital, supply chains, labor and equipment availability, and other factors and that the failure to act ''diligently'' to develop a lease has no adverse impacts on the environment. This is outlined in existing policy at Instruction Memorandum 2023–012, *Suspensions of Operations and/or Production,*[32] and the BLM agrees that the submission of an APD is a business decision for the lessee. The BLM has opted to incorporate this requirement in regulation, however, to ensure that BLM offices apply this requirement in the same way to promote fairness to all operators. The proposed changes provide definitive notice to operators and the BLM's authorized officers on processing these types of lease suspension, and therefore, the BLM did not make any changes based upon this comment.

Other commenters stated that the 90-day threshold proposed by the BLM is arbitrary, because there is no recorded evidence that the BLM can approve an APD in 90 days. The BLM proposed the 90 days based upon the BLM's average processing time for an APD across all BLM offices. The BLM provided this information in the preamble. In fiscal year 2022, the BLM's average processing time did increase to 162 days; however, the BLM decided to keep with the 90-day limit as it represents an average over a period of 3 years.

The commenters also recommended that instead of a set timeframe, the BLM should deny suspension requests based on a proposed action necessitating NEPA analysis, which cannot reasonably be completed prior to the lease expiration date; based on events the lessee could have and should have foreseen or avoided; and based on unknown, speculative, and or future events. Finally, the commenters recommended that the BLM should deny suspensions based upon adjacent unleased lands as the commenter considered these types of suspensions ripe for abuse and mismanagement. The BLM declines to make any changes to the rule based on these recommendations given the existing discretion of the authorized officer. For example, if the operator nominates adjacent unleased lands that are needed for development and are scheduled to be offered on an upcoming lease sale within the few months, the BLM does not see this as an unreasonable request.

Comments demonstrated confusion with the application of paragraph (c), seemingly believing that the APD submission requirement applies to all suspensions. This provision only applies when the applicant cites the pending APD as the sole basis for the suspension. If a lease needs to be suspended in the interest of conservation or for force majeure due to reasons other than a pending APD, then the BLM will not require an APD to be filed at least 90 calendar days prior to the expiration date of the lease. To remove the confusion, the BLM modifies the final rule by inserting the word ''only'' prior to the word ''cites.'' In addition, to increase readability, the BLM replaced the acronym ''APD'' with the words ''application for permit to drill'' as the BLM has not defined the acronym ''APD'' in part 3160.

In addition, one commenter stated that approving suspensions for only 1 year is arbitrary. The 1-year time frame ensures that suspensions are not granted for a longer period than necessary, and it provides a clear and easily trackable timeframe for both the BLM and lessees, which allows both parties to ensure compliance with applicable lease terms, such as the resumption of paying rentals or royalties. The BLM implemented an annual review of lease suspensions in Permanent Instruction Memorandum 2019–007, *Monitoring and Review of Lease Suspensions,*[33] after receiving GAO's recommendations in report GAO–18–411, *Oil and Gas Lease Management: BLM Could Improve Oversight of Lease Suspensions with Better Data and Monitoring Procedures.*[34] The BLM determined the 1-year timeframe was appropriate in this rulemaking because it conforms with BLM's existing policy. If, after a year, there is still a valid need for a suspension, a lessee may request a further extension.

Other commenters supported approving suspensions for 1 year; however, they also recommended that the BLM modify the final regulations to allow for only one extension to an oil and gas lease suspension. One commenter stated that the BLM should

[31] *https://www.blm.gov/sites/default/files/docs/2022-03/MS-3160-10%20Rel.%203-150.pdf.*

[32] *https://www.blm.gov/policy/im-2023-012.*

[33] *https://www.blm.gov/policy/pim-2019-007.*

[34] *https://www.gao.gov/products/gao-18-411.*

only grant additional suspensions in those situations where the lessee or operator is prevented from operating or producing due to force majeure. The BLM declines to accept this suggestion to limit suspensions to those based on force majeure because the MLA allows for suspensions of operations and production in the interest of conservation. The BLM will evaluate requests for suspension extensions to ensure the bases for the suspension remain valid, the operator has met any diligence requirements or other conditions of approval in the original approval, and the suspension is authorized by the MLA.

The BLM received several comments on paragraph (e) urging the BLM to modify this provision to only allow a directed suspension to last 1 year. The commenters claimed that long-term suspensions do not further the public interest or properly conserve natural resources and instead encumber public lands by making them unavailable for other uses and for other potential leaseholders, as well as fail to provide taxpayers with a fair return for the lease of public lands. The BLM declines to make this change. Given the reasons for which the BLM is authorized to issue a directed suspension, such as a court order, the suspension must remain in effect until the court allows operations.

24. Section-by-Section Discussion for Changes to 43 CFR Subpart 3171

The final rule does not make any revisions to the section designations or their headings in the existing 43 CFR subpart 3171 regulations.

Section 3171.14 Valid Period of Approved APD

The BLM received many comments on the proposed rule related to changing the term of an approved APD from the current 2 years with an optional 2-year extension to a 3-year term without extensions. The BLM received comments both in support and with concerns related to the proposed changes. After reviewing the comments, the BLM has made the following changes: (1) omitted the word ''ordinarily'' from paragraph (a); (2) clarified that the APD term in the regulations only applies to APDs approved after the effective date of the final rule; (3) clarified that the well must be drilled to total measured depth in paragraph (b); (4) clarified that paragraph (b)(1) includes wells drilled to approximate total measured depth and not yet completed; (5) stated that paragraph (b)(3) will only apply if the operator set the surface casing for the well and submits a plan to finish drilling and complete the well; (6) provided that the plan in paragraph (b)(3) must include the timeframe for continuously drilling and completing the well and any extenuating circumstances that may delay the continuous drilling and completion of the well; (7) specified that earthwork for reclamation must be completed within 6 months of the approved APD's expiration; and (8) added paragraph (e) to provide for the extension of an APD's term when the underlying lease is suspended.

Many commenters supported the BLM's proposal to extend the initial term of an approved APD from 2 to 3 years; however, multiple commenters recommended that the BLM establish a 4-year term for approved APDs. Commenters stated that a 4-year term for an approved APD would enable the BLM to process APDs efficiently and would provide consistency for industry. The BLM rejected this change, since approximately 95 percent of the approved APDs drilled under the existing regulations have been drilled within 3 years from the date of approval. By providing a set term without the option to extend, the BLM is providing more certainty for the industry to allow it to properly plan any operations. The remaining five percent may submit a new APD. Given the small percentage of operators who do not normally drill a well within 3 years of approval of an APD, the BLM believes the administrative burden on an operator of filing a new APD is justified in light of the BLM's interest in ensuring the public lands subject to an oil and gas lease are diligently developed.

One commenter encouraged the BLM to modify the rule and keep the current 2-year period for an approved APD with allowable extensions, stating the rule would have negative effects by increasing the BLM's administrative burden and requiring additional environmental review. The BLM disagrees. Currently, the BLM spends approximately 3,800 hours annually on processing APD extension requests. In some cases, the NEPA analysis is stale, and the BLM must complete a new analysis on the APD to verify that the impacts identified have not changed. This rule will reduce the administrative burden on both the BLM and the operator as extension requests would no longer be needed. The burden on the BLM would be further reduced by obviating the need for any potential additional NEPA analysis to support an extension. In addition, the 3 years in which to use an APD will provide sufficient time for 95 percent of the operators. Therefore, the BLM did not make any changes based upon this comment.

A commenter stated that changing the term of an approved APD from 2 years to 3 years without the possibility of an extension would kill many oil and gas projects before they ever get off the ground. The commenter supported this statement citing the length of time required to comply with NEPA. Without recourse to an extension, an operator is left without any means to maintain a lease. Often an operator is prevented from drilling due to circumstances completely out of their control. The comment encouraged the BLM to examine the negative effects the rule will have in this regard. The BLM believes the comment is confusing oil and gas lease suspensions and approved APD extensions. The BLM will still grant lease suspensions, which will allow an operator to maintain its lease if the suspension requirements are met, and which toll the running of the term of any previously issued permit to drill. This provision only addresses extensions for APDs. Moreover, even if a well is not drilled within the 3-year time period, as noted above, an operator can submit a new APD.

Another commenter recommended that the BLM omit the word ''ordinarily'' from paragraph (a) to avoid confusion. The comment stated that since ''ordinarily'' implies there is an exception, it is unnecessary with the ''notwithstanding'' clause, which is already addressed in paragraph (b). The BLM concurred with this recommendation and deleted the word ''ordinarily'' from paragraph (a).

In addition, one commenter requested that any change in terms to approved APDs only apply to the APDs approved and issued subsequent to the publication of a final rule. The BLM concurs with this recommendation. The BLM modified the final rule to clarify that the 3-year term only applies to APDs approved after the effective date of the rule. Consistent with general principles of retroactivity, any APD approved prior to the effective date of this rule will be eligible for a 2-year extension in accordance with the regulations in place when the BLM approved the APD.

For paragraph (b), a commenter requested that the rule specify either total vertical depth or total measured depth in the final rule. The BLM specifies total measured depth in the final rule as measured depths matches the requirements in an approved APD. A horizontal well drilled to total vertical depth would likely not be productive in paying quantities and would not meet the plans in the approved APD.

For paragraph (b)(1), a commenter requested that the BLM specify in the regulations that drilling, but not completing, would provide for the APD approval to remain valid. The BLM intended as much and has clarified the final rule by adding the statement ''including wells drilled to approximate total measured depth and not yet completed'' to paragraph (b)(1).

For paragraphs (b)(1) and (b)(2), a commenter recommended that the BLM set a time limit of one-year for any extensions beyond the initial term of the APD based on the criteria outlined in the proposed regulation. The BLM declines to provide for a further extension of an APD under either (b)(1) or (b)(2). In both of these scenarios, a well has already been drilled to the approximate total measured depth as authorized by the APD. Instead, the BLM will administer the wells as shut-in or temporarily abandoned if the well is not yet producing at the expiration of the APD. This allows the BLM to track and manage these wells under 43 CFR 3162.3–4. Therefore, there is no need to set a limit of one-year for paragraphs (b)(1) and (b)(2) in this section.

The BLM received multiple comments on paragraph (b)(3). Some commenters considered the requirement for the plan to be vague and that the regulatory language leaves the authorized officer with no guidance for approving such a plan. A separate comment recommended that the BLM accept reasonable plans to complete drilling any well to total depth if the operator has set surface casing prior to the APD expiring. The BLM reviewed the many comments on the plan required by this section and recognized that more information on the plan should be added to the regulations. Based on these comments, the BLM has revised paragraph (b)(3) to specify that the ''plan must include the timeframe for continuously drilling and completing the well and any extenuating circumstances that may delay the continuous drilling and completion of the well.''

In addition, multiple commenters encouraged the BLM to delete paragraph (b)(3). They asserted that paragraph (b)(3) would allow APD extensions based only on submission of a drilling plan to the BLM, with no requirement that on-the-ground activity have taken place, undermining the goal of diligent development. They further contended it may risk further waste of public lands and resources. The BLM concurs that the operator should be pursing diligent development with a showing of on-the-ground activity. The BLM modified paragraph (b)(3) to require that on-the-ground activity has taken place to ensure the operator has started development under the APD. For the final rule, the BLM updated paragraph (b)(3) to require the operator to have set the surface casing for the well and to have submitted a plan. This will ensure the operator is working towards developing its lease with a real effort to begin development. In addition, as noted above, one comment recommended the BLM accept reasonable plans to complete drilling any well to total depth if the operator has set surface casing prior to the APD expiring. Therefore, the BLM considered requiring surface casing for the BLM to consider a plan as a reasonable approach for paragraph (b)(3).

For paragraph (c), a commenter expressed concern that an operator may not be able to submit an APD to finish drilling the well during the time allowed under the proposed regulations, and the regulations would then require the operator to immediately comply with all applicable plugging, abandonment, and reclamation requirements. This was not the intent in the proposed rule; therefore, the BLM updated the final rule to provide two options for an expired APD. The ''operator or lessee must either comply with all applicable plugging, abandonment, and reclamation requirements or submit a new APD covering the existing disturbance.''

The BLM received a comment on paragraph (d) suggesting that the BLM should specify the timeframe by which reclamation must start once an APD expires. The BLM's existing regulations require earthwork for reclamation to begin within 6-months of well completion or well plugging under 43 CFR 3171.25(b)(2). To be consistent with 43 CFR 3171.25(b)(2), the final rule updates paragraph (d) to state, ''Earthwork for reclamation must be completed within 6 months of APD expiration (weather permitting).''

Multiple commenters expressed concern that the BLM proposes to no longer grant extensions to an APD's term. Some commenters expressed a concern that the lack of an APD extension would disadvantage project proponents in situations where drilling was delayed for a variety of on-the-ground reasons and there is not a way to seek an APD extension. Another commenter mentioned the need for extensions when there is litigation challenging the NEPA compliance for the lease or APD because the BLM cannot take any action on an APD when there is ongoing litigation. Upon review of the comments, the BLM recognizes that there is a valid concern related to litigation challenging the issuance of leases; therefore, the BLM added paragraph (e), which will allow the BLM to adjust an APD's term when the lease is suspended. The new paragraph (e) states, ''The valid period for an approved APD on a lease suspended under subpart 3103 will be adjusted to account for the suspension. Beginning on the date the suspension is lifted, the valid period of the approved APD will be extended by the time that was remaining on the term of the approved APD on the effective date of the suspension.'' This addition will allow the BLM to extend the term of an approved APD based upon an oil and gas lease suspension of operations and/or production. The BLM will not grant general extensions as the 3-year APD term will provide sufficient time for the Federal operator to drill a well under an approved APD.

25. Section-by-Section Discussion for Changes to 43 CFR Subpart 3181

The BLM identified that 43 CFR 3181.5 should be updated to recognize the changes to royalty made by the IRA. The BLM has revised the existing § 3181.5 in the final rule to reflect the increased royalty rate.

Finally, the rule will not make any revisions to the section designations or their headings in the existing 43 CFR subpart 3181 regulations.

Section 3181.5 Compensatory Royalty Payment for Unleased Federal Land

During the public comment period, the BLM discovered that § 3181.5 of the current regulations still references a royalty rate of 12.5 percent. As discussed earlier, in the IRA, Congress changed the royalty rate for onshore Federal oil and gas leases to 16.67 percent, a rate that will last until August 2032, at which time, the royalty rate becomes not less than 16.67 percent and subject to further increases. Therefore, the BLM is replacing the 12.5 percent royalty in § 3181.5 with the language ''the current royalty percentage for leases offered on onshore oil and gas lease sales.'' This will allow BLM offices to enter the appropriate royalty rate based upon the latest onshore oil and gas lease sales for the area.

26. Section-by-Section Discussion for Changes to 43 CFR Subpart 3186

During the comment period, BLM employees identified that a section in the model onshore unit agreement for unproven areas should be updated to recognize the changes Congress made to royalty rates in the IRA.

Section 3186.1 Model Onshore Unit Agreement for Unproven Areas

Section 17(b) of the model onshore unit agreement for unproven areas still references the old royalty rate of 12.5 percent. Because Congress changed the royalty rate in the IRA for onshore Federal oil and gas leases to 16.67 percent, the BLM is replacing the 12.5 percent royalty in Section 17(b) of the model onshore unit agreement for unproven areas with the language ''(current royalty for leases offered on onshore oil and gas lease sales).'' This will allow BLM offices to enter the appropriate royalty rate based upon the latest onshore oil and gas leases.

The BLM is republishing the revised model onshore unit agreement for unproven areas in the final rule in its entirety because the OFR is unable to make a piecemeal edit to the document. The document is not regulatory and, in conformance with current OFR Document Drafting Handbook requirements, cannot be given section numbers. Instead, the model onshore unit agreement for unproven areas must be redesignated in the final rule as Appendix A to Part 3180. The BLM uses this model form to identify where new unit agreements do not match the model form and ensures any differences from the model form are in the public interest.

Likewise, at the direction of the OFR, the BLM is redesignating four other models and exhibits that comprise the remainder of existing subpart 3186. These items will appear in the final rule as follows: (1) § 3186.1–1 Model ''Exhibit A'' will appear as Appendix B to Part 3180; (2) § 3186.1–2 Model ''Exhibit B'' will appear as Appendix C to Part 3180; (3) § 3186.3 Model for designation of successor unit operator by working interest owners will appear as Appendix D to Part 3180; and (4) § 3186.4 Model for change in unit operator by assignment will appear as Appendix E to Part 3180. The final rule does not revise the contents of Appendices B through E.

Cross refences in §§ 3107.10(a), 3181.1 and 3183.4(a) are revised in the final rule to reflect the redesignated appendices.

Procedural Matters

A. Regulatory Planning and Review (E.O. 12866, E.O. 14094, E.O. 13563)

E.O. 12866, as amended by E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this final rule constitutes a ''significant regulatory action'' within the scope of section 3(f)(1) of E.O. 12866, as amended by E.O. 14094.

During the comment period for the proposed rule, some commenters suggested that the proposed rule would cause adverse effects on the economy, the energy sector of the economy, and all communities that rely on fluid mineral development as their major economic driver. Commenters pointed to the language in the preference criteria for leasing under § 3120.42, asserting it could severely restrict the amount of oil and gas leasing on Federal lands. The BLM disagrees. Codifying the preference criteria will ensure that oil and gas leasing on public lands focuses development where there is the most potential for recovery and allows the agency to manage public lands for other uses. The BLM completed an RIA and determined that the net costs to the economy range from a cost of $8.0 million to a cost of $13.2 million, depending on the cost of bonds (1 percent or 2 percent) and the number of wells the BLM reclaims (15 wells or 24 wells). As discussed in the RIA, the BLM expects that the expedited timing for reclamation of orphaned wells from increased bonding could provide benefits related to wildlife, vegetation, soil erosion, climate change (reduced greenhouse gas emissions from unplugged orphaned wells), visual and aesthetic resources, ground water, and allowing the surface land to be utilized for other uses sooner (for example, for grazing purposes). The BLM cannot currently quantify these benefits using the information available to the BLM.

Other benefits of the final rule include ensuring that costs reside with oil and gas lessees, operating rights owners, and operators, and not the American public. This includes adjusting the BLM's cost recovery mechanisms so that project applicants provide a more equitable share of the BLM's up-front costs for processing these applications. Finally, the BLM implements several changes to provide a transparent leasing process that focuses leasing on areas with a greater likelihood of being developed with fewer resource conflicts and ensuring transparency in these processes. Overall, shifting the financial responsibility for leasing to industries and ensuring transparency in the decision-making process will result in a more effective, fair, and accountable regulatory framework that benefits both businesses and society as a whole.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas.

This final rule replaces the BLM's current rules governing oil and gas leasing, which are contained in 43 CFR 3100 through 3140, and revises some regulations governing oil and gas operations, which are contained in 43 CFR 3150 through 3171.

For any regulatory action that OIRA determines is a significant regulatory action under section 3(f)(1) of E.O. 12866, section 6(a)(3)(C) of E.O. 12866 requires Federal agencies to provide an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable non-regulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives. 58 FR 51735, 51741. The BLM developed this final rule in a manner consistent with the requirements in E.O. 12866 and E.O. 13563.

For more detailed information on the BLM's analysis, as required by the referenced Executive Orders, see the RIA prepared for this final rule. The RIA has been posted in the docket for the final rule on the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Searchbox, enter ''RIN 1004–AE80'', click the ''Search'' button, open the Docket Folder, and look under Supporting Documents.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires that Federal agencies prepare a regulatory flexibility analysis for rules subject to the notice-and-comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), if the rule would have a significant economic impact, whether detrimental or beneficial, on a substantial number of small entities. See 5 U.S.C. 601–612. Congress enacted the RFA to ensure that government regulations do not unnecessarily or disproportionately burden small entities. Small entities

include small businesses, small governmental jurisdictions, and small not-for-profit enterprises.

The BLM reviewed the Small Business Administration's (SBA) size standards for small businesses and the number of entities fitting those size standards as reported by the U.S. Census Bureau in the Economic Census. The number of small businesses in States where there are existing Federal oil and gas leases is estimated to be 20,975 for the Crude Petroleum Extraction and Natural Gas Extraction industries (North American Industry Classification System (NAICS) codes 211120 and 21130, respectively). The BLM concludes that the vast majority of entities operating in the relevant sectors are small businesses as defined by the SBA. As such, the final rule will likely affect a substantial number of small entities.

In addition, the rule will have a distributional and positive impact on the Direct Property and Casualty Insurance Carriers Industry (NAICS 524126). Additional premiums will be paid by lessees in the oil and natural gas extraction industries to surety companies who will be providing the coverage to meet the proposed bonding requirements. The number of small businesses in the oil and gas industry in States where there are existing Federal oil and gas leases is estimated to be 476,687. This is because the SBA defines a small business for purposes of the Crude Petroleum Extraction and Natural Gas Extraction industries (NAICS codes 211120 and 21130, respectively) as one which has 1,250 or fewer employees.

Finally, the BLM received multiple comments expressing concerns related to impacts that the proposed rule would have on small entities. Specifically, the comments stated that: (1) the BLM should have included the changes from the IRA in its analysis for the Regulatory Flexibility Act (RFA); (2) the BLM should have mailed notification of the proposed rule to the affected small businesses under the RFA; (3) the BLM should have considered alternatives as required by the RFA; and (4) this rule requires the preparation of an initial and final Regulatory Flexibility Analysis. The BLM reviewed the final rule and has determined that, although the final rule will likely affect a substantial number of small entities, that effect will not be significant. The basis for this determination is explained in more detail in the RIA.

Because the increased royalty amounts, bonus bids, and rentals, and the EOI fee, are non-discretionary, the BLM is not required to include these increases in its evaluation of the impacts on small businesses. Congress passed the RFA ''to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' Public Law 96–354, section 2(b), 94 Stat. 1164 (1980). The RFA requires agencies to analyze alternatives to their rules with an eye towards minimizing significant impacts on small entities. 5 U.S.C. 603(c), 604(a)(6). In this case, the BLM cannot consider alternatives to mandatory instructions in the IRA. The nondiscretionary changes include the increased minimum bonus bid, rental, and royalty rate, and the new EOI fee. The only discretionary cost increases at issue in this final rule are the increased bonding amounts and filing fees, which are fully analyzed. Aside from assessing alternatives to the statutorily mandated provisions of this rule, however, the BLM has provided the analysis the RFA requires.

Based on the BLM's review of the costs associated with the increased bonding, the BLM has determined that the incremental costs that a company must pay to meet the increased bonding amounts are unlikely to deter a company from obtaining a lease and developing it. As discussed in the RIA, sureties offer both new and existing operators the ability to cover the increased bond amount at an estimated cost of only 1 to 2 percent per year of the additional bond amount.

While there were multiple comments stating that small operators will be forced to shut in wells, will be at higher risk of going bankrupt, or will go bankrupt due to the increased costs, the comments did not provide the well- or lease-level financial information needed to support these claims. The BLM reviewed available data and reported statistics on the sensitivity of low-producing wells to changes in wellhead prices and concluded that, given the range of recent and expected oil prices, even low-producing wells generate sufficient revenue to fund the increased level of bonding. The economic data provided from the public comment period did not provide the necessary detail to support a more detailed analysis. For example, one commenter provided a report on the economic benefits of oil and gas leasing. This report supported our baseline in the RIA; however, it did not change the BLM's estimates of the impacts from this rule.

Notably, the BLM has only limited access to financial data of the small businesses themselves, since most of those small businesses are privately held and are not required to report their financial information to the BLM or any other public forum. Even if a company is public, those covered under the NAICS codes for Crude Petroleum and Natural Gas Extraction are often partnerships or limited liability companies, which frequently merge and split, making it difficult to determine if a firm composed of partners and subsidiaries are sufficiently affiliated to be considered small businesses or if they are functionally a subsidiary of a larger firm. Even when financial statements are available for review, those statements are designed to standardize overall reporting of an entity's finances and do not specify income and expenditures associated with production from Federal wells. Nor is it possible to obtain the requisite information on both Federal production volume and the production costs of this Federal production from any Federal database. For example, ONRR reports production volumes but not production costs. Constructing the needed data on Federal production and financial costs requires cross-referencing several data sources that are not readily available.

Therefore, based on the BLM's review, the BLM lacks the data to determine whether the rule will impact small businesses in the manner the commenters assert. Nor is such information reasonably available to the BLM such that it could undertake such analysis. The BLM has, nevertheless, reaffirmed its finding that the rule will not have a significant impact on a substantial number of small entities for the reasons described above in this section.

In summary, the per-entity, annualized compliance costs associated with this final rule are estimated to represent only a small fraction of the annual net incomes of the companies likely to be impacted. Because the final rule will not have a ''significant economic impact on a substantial number of small entities,'' neither an initial nor a final regulatory flexibility analysis is required.

The Secretary of the Interior 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.

C. Congressional Review Act

The Congressional Review Act (5 U.S.C. 804(2)) requires certain procedures for ''any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—

a. an annual effect on the economy of $100 million or more;

b. a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions;

c. significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

DOI will report to Congress on the promulgation of this rule prior to its effective date. The report will state that the Office of Information and Regulatory Affairs has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2).

D. Unfunded Mandates Reform Act (UMRA)

The final rule will not have a significant or unique effect on State, local, or Tribal governments or the private sector. The rule contains no requirements that apply to State, local, or Tribal governments. The rule revises requirements that otherwise apply to the private sector participation in a voluntary Federal program. The compliance costs associated with the rule are below the monetary threshold established at 2 U.S.C. 1532(a). The rule updates the BLM's existing regulations to reflect the IRA's changes to lease terms. Those provisions (which became effective with the enactment of the IRA and which the BLM has no discretion to modify) will result in additional transfer payments made from the private sector to the U.S. Treasury, which then distributes portions to State governments and various funds, such as the Land and Water Conservation Fund. The BLM estimates the transfer payments will total $210 million per year, but these payments are not a result of action taken by the BLM and are instead Congressionally mandated. Since the discretionary provisions of the rule impose compliance costs that are below the $100,000,000 threshold established at 2 U.S.C. 1532(a), a statement containing the information required by the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531 *et seq.*) is not required for the final rule. This final rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments, because it contains no requirements that apply to such governments, nor does it impose obligations upon them. In any event, this rule and the accompanying Regulatory Impact Analysis provide all the information the UMRA requires.

E. Governmental Actions and Interference With Constitutionally Protected Property Right—Takings (E.O. 12630)

This final rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630; therefore, a takings implication assessment is not required. The final rule replaces the BLM's current rules governing oil and gas leasing, which are contained in 43 CFR 3100 through 3140, and some governing oil and gas operations, which are contained in 43 CFR 3160 and 3171. Therefore, the rule will impact future leases on Federal land; however, it will not impact current leases. All other terms in the regulations are not considered a taking of private property as such operations are subject to the existing lease terms which expressly require that subsequent lease activities be conducted in compliance with subsequently adopted Federal laws and regulations.

This final rule conforms to the terms of the existing leases and applicable statutes and, as such, the rule is not a government action capable of interfering with constitutionally protected property rights. Therefore, the BLM has determined that the rule will not cause a taking of private property or require further discussion of takings implications under E.O. 12630.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this final rule does not have any federalism implications to warrant the preparation of a federalism summary impact statement.

The final rule will not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the levels of government. It does not apply to States or local governments or State or local governmental entities. The rule will affect the relationship between operators, lessees, and the BLM, but it does not directly impact the States. Therefore, in accordance with E.O. 13132, the BLM has determined that this final rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Several commenters suggested that the BLM should make substantial changes to the rule to allow for better cooperation with States and local governments when their jurisdictions overlap. For example, one comment stated that the BLM must respect local governments' regulatory authority over State, private, and trust mineral and water resources within each State. Another comment stated that the proposed rule would have significant direct impacts on the States and local communities, and that, if the BLM does not offer Federal lands for lease, that omission will prevent State and private lessees from developing their leases due to the mixed ownership for horizontal wells. Some comments stated the rule is inconsistent with State laws that expedite the processing, granting, and streamlining of mineral and energy leases and permits.

The BLM developed this rule based on its statutory authority to offer federally owned lands and minerals for oil and gas leasing and development. The BLM has evaluated the federalism implications of this rule as required by E.O. 13132. Although the final rule will affect the relationship between operators, lessees, and the BLM, it will not directly impact the States' leasing ability. Local governments and the public may submit information to the BLM on how the development of nominated lands may affect the development of adjacent non-Federal lands when the BLM is considering lands for leasing. This could occur either when the EOI is submitted or during the scoping and public comment periods for the lease sales.

G. Civil Justice Reform (E.O. 12988)

This final rule complies with the requirements of E.O. 12988. More specifically, this final rule meets the criteria of section 3(a), which requires agencies to review all regulations to eliminate errors and ambiguity and to write all regulations to minimize litigation. This final rule also meets the criteria of section 3(b)(2), which requires agencies to write all regulations in clear language with clear legal standards.

H. Consultation and Coordination With Indian Tribal Governments (E.O. 13175 and Departmental Policy)

The Department strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their

right to self-governance and tribal sovereignty.

The BLM evaluated this final rule under the Department's consultation policy and under the criteria in E.O. 13175 to identify possible effects of the rule on federally recognized Indian Tribes. Since the changes to leasing only apply to Federal lands, the final rule will not impact the leasing of Indian minerals. The final rule could impact Tribal minerals as the BLM will require operators on both Federal and Tribal minerals to comply with the requirements within Parts 3160 and 3170, including the changes for shut-in and temporarily abandoned wells and approved APDs.

In August of 2021, the BLM sent a letter to each registered Tribe informing them of certain rulemaking efforts, including the development of this final rule. The letter offered Tribes the opportunity for individual government-to-government consultation regarding the rulemaking.

In June 2023, the BLM sent another letter to each registered Tribe informing them of the proposed rule. During the comment period for the proposed rule, a commenter, who is not from a Tribe, stated that the BLM should fulfill its Federal trust obligation to Tribes to protect their interest and further the government-to-government relationships with Tribes. The BLM concurs and worked to inform the Tribes of the changes proposed in this rulemaking. The BLM did receive comments from a Tribe as previously discussed in Section III.B.4. and III.B.8. of this preamble.

I. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521) generally provides that an agency may not conduct or sponsor, and not withstanding 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. Collections of information include any request or requirement that persons obtain, maintain, retain, or report information to an agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)).

This final rule contains information-collection requirements that are subject to review by OMB under the PRA. OMB has generally approved the existing information collection requirements contained in the regulations that will be affected by this final rule under the following OMB Control Numbers:

- 43 CFR 3100, 3120, and subpart 3162—OMB Control Number 1004–0185;
- 43 CFR 3106—OMB Control Number 1004–0034;
- 43 CFR part 3130—OMB Control Number 1004–0196;
- 43 CFR 3150—OMB Control Number 1004–0162; and
- 43 CFR 3160—OMB Control Number 1004–0137.

The BLM plans to transfer the information collection requirements contained in 43 CFR 3106 from OMB control number 1004–0034 to OMB Control Number 1004–0185 in order to keep similar information collections requirements together under the same OMB Control Number. Additionally, the BLM plans to transfer information collection requirements contained in 43 CFR 3160 from OMB Control Number 1004–0137 to a new OMB Control Number. Once approved by OMB, the new OMB Control Number will be 1004–0220. The new and revised information collection requirements are discussed as follows, along with the resulting changes in public burdens.

1. Changes Impacting Information Collections Previously Under OMB Control Number 1004–0137

The final rule will result in new information collection requirements that will require OMB approval under a new OMB control number (previously, 1004–0137). This final rule is estimated to result in 33,621 annual responses, 260,928 annual burden hours, $35,400,000 non-hour cost burdens under this new OMB Control Number.

The new information collection requirements are described as follows.

43 CFR 3162.3–4 Well Abandonment. The final rule requires that no well may be abandoned for more than 30 days unless the operator provides adequate and detailed justifications and verification of the mechanical integrity of the wells and isolation of the perforations. The new information collection requirements include:

- Justification for Temporary Well Abandonment—43 CFR 3162.3–4(d);
- Reporting Shut-in Status—43 CFR 3162.3–4(e);
- Verification of Mechanical Integrity—43 CFR 3162.3–4(e)(2) and 3162.3–4(f); and
- Plan and Timeline for Future Beneficial Use—43 CFR 3162.3–4(e)(3)(iii).

The BLM believes these new requirements with yearly interval checks will help operators stay on top of shut-in wells, thus preventing them from becoming orphaned in the future. The addition of these information collection requirements will result in an addition of 5,500 annual responses, 52,000 annual burden hours.

Currently, there are 301,663 annual responses, 1,835,888 annual burden hours, and $31,080,000 annual non-hour cost burdens inventoried under the OMB Control Number 1004–0137. This final rule will create a new OMB Control Number and moves 28,121 annual responses, 208,298 annual burden hours, and $31,080,000 annual non-hour cost burdens inventoried under OMB Control Number 1004–0137 into this OMB Control Number.

In addition, there is an adjustment of $4.3 million in annual non-hour cost burdens (from $31 million to 35.4 million). This adjustment results from the annual inflation adjustment of filing fees and do not result from the final rule. The resulting new estimated total burdens for this new OMB Control Number are provided as follows.

Title of Collection: Onshore Oil and Gas Operations and Production (43 CFR parts 3160 and 3170).

OMB Control Number: 1004–0220.

Form Numbers: BLM Form 3160–003; BLM Form 3160–004; and BLM Form 3160–005 (these forms will not change).

Type of Review: Revision of a currently approved collection of information.

Respondents/Affected Public: Oil and gas operators on public lands and some Indian lands.

Total Estimated Number of Annual Respondents: 7,500.

Total Estimated Number of Annual Responses: 33,621.

Estimated Completion Time per Response: Varies from 4 to 32 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 260,928.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion; One-time; and Monthly.

Annual Burden Cost: $35,400,000.

2. Changes Impacting OMB Control Number 1004–0162

Currently, there are 68 annual responses, 26 annual burden hours, and $25 annual non-hour cost burdens inventoried under OMB Control Number 1004–0162. It is not anticipated that the final rule will change the results to the annual responses, annual burden hours, or non-hour cost burdens under this OMB Control Number. The revised information collection requirement is described as follows.

43 CFR 3151.30—Collection and submission of data. The final rule adds a new requirement for the permittee to provide the BLM with all data and

information obtained in carrying out the exploration plan, matching the requirement for geophysical exploration permits in Alaska. This does not change the existing burden for what applicants to submit to the BLM.

Title of Collection: Onshore Geophysical Exploration (43 CFR part 3150 and 36 CFR parts 228 and 251).

OMB Control Number: 1004–0162.

Form Number: BLM 3150–4/FS 2800–16; BLM 3150–5/FS 2816a (these forms will not change).

Type of Review: Revision of a currently approved collection of information.

Respondents/Affected Public: The respondents for this collection of information are businesses that seek to conduct geophysical exploration on Federal lands.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: On occasion.

Estimated Completion Time per Response: Varies from 20 minutes to 1 hour, depending on activity.

Number of Respondents: 68.

Annual Responses: 68.

Annual Burden Hours: 26.

Annual Burden Cost: $1,150.

3. Changes Impacting OMB Control Number 1004–0185

Currently, there are 9,132 annual responses, 37,695 annual burden hours, and $751,415 annual non-hour cost burdens inventoried under OMB Control Number 1004–0185. This final rule is estimated to result in 16,340 annual responses, 29,410 annual burden hours, $3,766,184, non-hour cost burdens under this OMB Control Number. The final rule will result in new, revised, and removed information collection requirements. Additionally, as discussed earlier, the BLM will also be transferring certain information collection requirements, along with the associated burdens from OMB Control Number 1004–0034 to OMB Control Number 1004–0185. These changes are discussed blow.

Revised Information Collection Requirements

43 CFR 3100.31(b)—Option Enforceability. The final rule revises this requirement to clarify that a statement of the number of acres and the type and percentage of interest to be conveyed and retained by the parties to the option. This does not change the burden requirement. The existing regulation already states the interest to be conveyed and retained in exercise of the option. The BLM needs to understand if the type of interest is referring to record title or operating rights and the percentage to be conveyed and retained by the option holder.

43 CFR 3105.21—Where to File Communitization Agreements. The final rule removes the triplicate filing requirement. The final rule adds a new paragraph (b) to this section to require that all applications to form a CA be filed with a statement as to whether the proposed CA deviates from the BLM's current model CA form, and a certification that the applicant received the required signatures. Further, all applications to form a CA shall include an Exhibit A displaying a map of the agreement and the separate agreement tracts and all applications to form a CA shall include an Exhibit B displaying the separate tracts and ownership. The new paragraph (c) states that all applications to form a CA should be submitted at least 90 calendar days prior to first production to ensure correct reporting to the ONRR. These requirements codify existing policy requirements and does not change the existing burden for what applicants to submit to the BLM. The information is needed to understand all the parties that share in the production of a well due to State spacing orders.

43 CFR 3105.31—Where filed. (Operating, Drilling or Development Contracts). The final rule removes the requirement for five copies of an operating, drilling or development contract to be submitted when these contracts are submitted to the BLM for approval. This reduces the burden to respondents.

43 CFR 3105.41—Where filed. (Subsurface storage application (previously, 3105.5)). The final rule designates the existing 43 CFR 3105.5 for gas storage agreements to the redesignated 43 CFR 3105.41. This redesignation is due to the elimination of the section on the combination for joint operations or for transportation of oil. The final rule updates paragraph (a) to include designation of successor operators for gas storage agreements among the applications to be filed in the proper BLM office. The final rule updates paragraph (b) to remove the requirement for five copies of a gas storage agreement to be submitted when these are filed with the BLM. A new paragraph (c) requires that all applications for a gas storage agreement or a designation of a successor operator must include the new processing fee found in the fee schedule in 43 CFR 3000.120. The new processing fee is intended to reimburse the BLM for processing the applications.

43 CFR 3105.50—Consolidation of Leases (formerly, 3105.6). Leases may be consolidated upon written request of the lessee filed with the proper BLM identify each lease involved by serial number and shall explain the factors that justify the consolidation and requires that each request for a consolidation of leases the processing fee found in the fee schedule in 43 CFR 3000.120. The final rule splits the single paragraph under this section into several paragraphs for clarity, however these are not new requirements and does not change the existing burden.

43 CFR 3106.81—Heirs and devisees. The updates this information collection requirement to state that the lease interest will be transferred to the heirs, devisees, executor or administrator of the estate, as appropriate, upon the filing of a court order, death certificate, or other legal document demonstrating that transferee is to be recognized as the successor of the deceased. These requirements codify existing policy requirements and does not change the existing burden for what applicants currently submit to the BLM to show proof on how the lease interest transferred to another party.

43 CFR 3106.82—Change of name. The current regulation requires a notice of the name change to be accompanied by a list of the serial numbers of the leases affected by the name change. This requirement is removed as it is outdated and unenforceable. This lessens the burden to respondents. In practice, the BLM generates a report of the leases affected by the name change and returns that list to the lessee with a notice that recognizes the name change that occurred through operation of law. This section is updated to require that, for a corporate name change, the request should include the Secretary of State's Certificate of Name Change along with the Articles of Incorporation, or Amendment, if available. This is consistent with the BLM's current approach for processing these types of documents. These requirements codify existing policy requirements and does not change the existing burden for what applicants currently submit to the BLM to show proof on how the lease interest transferred to another party.

43 CFR 3106.83—Corporate mergers and dissolution of corporations, partnerships and trusts. The final rule updates the title of this section from ''Corporate merger'' to ''Corporate mergers and dissolution of corporations, partnerships and trust''. The goal of the renaming of this section is to incorporate these other types of transfers that have the same process. The current regulation requires a notification of merger to be accompanied by a list of the serial numbers of the leases affected by the

merger. This requirement is eliminated as it is outdated and unenforceable. This lessens the burden to respondents. In practice, the BLM does not rely on a list of leases provided by a lessee and instead generates its own report of the leases affected by the merger. The BLM returns that list to the lessee with a notice that recognizes the merger that occurred through operation of State law. This section is updated to require that, for a merger, the request should include the Secretary of State's Certificate of Merger along with the Articles of Incorporation, or Amendment, if available. This is consistent with the BLM's current approach for processing these types of documents. These requirements codify existing policy requirements and does not change the existing burden for what applicants currently submit to the BLM to show proof on how the lease interest transferred to another party.

43 CFR 3108.23—Reinstatement at higher rental and royalty rates: Class II reinstatements. The final rule eliminates the existing paragraph (b)(1) in its entirety. This provision addresses the timeliness of Class II reinstatement petitions for leases that terminated on or before August 8, 2005, and is no longer applicable. This does not change an existing burden since a petition to reinstate a lease that terminated on or before August 8, 2005, would have already been received by an applicant.

43 CFR 3109.12—Application. The final rule also adds a new requirement that the applicant must include a map of the applicable lands which will support the bidding process related to the lease or compensatory royalty agreement. These requirements codify existing policy requirements and does not change the existing burden for what applicants to submit to the BLM.

New Information Collection Requirements

43 CFR 3106.84—Sheriff's sale/deed. The final rule adds a new section under other types of transfers to include sheriff's sales. The BLM accepts these types of transfers to recognize lease interests transferred to other parties through foreclosure actions. The final rule states that where a notice of sale of the leasehold interest is published pursuant to State law applicable to the execution of sales of real property, the purchaser shall submit a copy of the Sheriff's Certificate of Sale after any redemption period has passed to the proper BLM office. Additional paragraphs under this new section include a filing fee requirement, a qualification statement, and bonding requirements. These requirements are consistent with the BLM's current approach for processing these types of documents. These documents are already submitted and recognized by the BLM when changes in ownership of interests in Federal oil and gas leases occur without any intention by the holder of interest to assign or transfer interest. The addition of this information collection will result in an addition of 1 annual response, 1 annual burden hour, and $55.80 annual non-hour cost burdens.

43 CFR 3120.31—Expression of Interest (EOI) Process. The final rule adds a new section titled ''Expression of Interest'' to codify the current process of receiving EOIs for competitive leasing to the BLM's online leasing system. An EOI is a description of lands that an applicant seeks to include in a competitive auction. The expression must provide a description of the lands identified by legal land description and identify the U.S. mineral ownership percentage. This information collection will result in an addition of 395 annual responses (average of 1,000 acres per response), 3,160 annual burden hours, and $1,975,000 annual non-hour cost burdens (calculated by average acreage per response).

Removed Information Collection Requirements

43 CFR 3101.2–6—Ad Hoc Acreage Statement. At any time, the BLM may require a lessee or operator to file a statement showing as of the specified date, the serial number and the date of each lease in which the lessee or operator has any interest, in the particular State, setting forth the acreage covered thereby. The BLM uses the information to determine whether or not a lessee is in compliance with the law with respect to statutory acreage limitations. This revision results in the reduction of 1 response and 1 burden hour, annually.

43 CFR 3105.4—Combination for joint operations or for transportation of oil. The final rule eliminates the section on the combination for joint operations or for transportation of oil. These provisions are not used by the BLM or operators and are outdated. This revision results in the reduction of 1 response and 1 burden hour, annually.

43 CFR 3107.8—Renewal leases. The final rule eliminates the provisions on renewal leases in their entirety because they are outdated. Renewal leases that had an expiration date after November 15, 1990, were eligible for one last renewal under the provisions of the November 15, 1990, Act, *i.e.,* for 10 years, and for so long thereafter as oil and gas is produced in paying quantities. If a lease was renewed after the 1990 amendment and was not producing oil or gas at the end of its 10-year renewal term, the lease expired with no further option for renewal. The removal of this information collection will result in a reduction of 1 annual response, 1 annual burden hour, and $475 annual non-hour cost burdens.

Class III reinstatement petition (43 CFR 3108.2–4). The requirement is removed from the final rule resulting in a reduction of one annual response and one burden hour as well as $651 in non-hour cost burden.

Information Collection Requirements Transferred From OMB Control Number 1004–0034

The following two information collections will be moved into OMB Control Number 1004–0185 to keep information collection requirements in subpart 3106 under the same OMB Control Number:

1. *43 CFR 3106.41, Transfers of record title and of operating rights (subleases) and 3106.42, Transfers of other interests, including royalty interests and production payments.* This transfer will result in 3,852 annual responses, 1,926 annual burden hours, and $404,460 non-hours cost burdens being added to this OMB Control Number.

2. *43 CFR 3106.43 Mass transfers.* This transfer will result in 4,944 annual responses, 2,472 annual burden hours, and $519,120 non-hours cost burdens being added to this OMB Control Number.

The resulting new estimated total burdens for OMB Control Number 1004–0185 are provided as follows.

Title of Collection: Onshore Oil and Gas Leasing, and Drainage Protection (43 CFR parts 3100, 3120, and 3150, and subpart 3162).

OMB Control Number: 1004–0185.

Form Number: None.

Type of Review: Revision of a currently approved collection of information.

Respondents/Affected Public: Holders of onshore oil and gas lease and public lands and Indian lands (except on the Osage Reservation), operators of such leases, and holders of operating rights on such leases.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: Varies from 1 hour to 24 hours per response, depending on activity.

Number of Respondents: 16,339.

Annual Responses: 16,340.

Annual Burden Hours: 29,410.

Annual Burden Cost: $3,766,184.

4. Changes Impacting OMB Control Number 1004–0196

Currently, there are there are 21 annual responses and 220 annual burden hours associated with this OMB control number. There are also no non-hours cost burden currently associated with this OMB control number. The final rule is not projected to result in any new annual responses. The additional requirements in 43 CFR 3170.80(b) include description of the anticipated PA(s) size and define the proposed PAs in the unit designation agreements required by 43 CFR 3137.21, and 3137.23 is not projected to result in additional burden for that information collection.

43 CFR 3000.120 introduces new filing fees for the following information collections, resulting in a new total estimated annual non-hour burden cost of $1,320;

- $120 for Statement of change of unit operator (43 CFR 3137.61); and
- $1,200 for Application for storage agreement (43 CFR 3138.11);

Additionally, the existing 43 CFR 3137.86, New information demonstrating that the participating area should be larger or smaller than previously determined, contains the following three information collection requirements for which the burden has not been previously captured in this OMB control number:

- Information demonstrating that a participating area should be larger than previously determined (43 CFR 3137.86(a)(1));
- Application to enlarge participating area outside of existing boundaries (43 CFR 3137.86(a)(2)); and
- Statement for additional committed tract or tracts are added to the unit under paragraph (a)(2) (43 CFR 3137.86(a)(3)).

The resulting new estimated total burdens for OMB Control Number 1004–0196 are provided as follows.

Title of Collection: Oil and Gas Leasing: National Petroleum Reserve—Alaska (43 CFR part 3130).

OMB Control Number: 1004–0196.

Form Number: None.

Type of Review: Revision of a currently approved collection of information.

Respondents/Affected Public: Participants within the oil and gas leasing program within the National Petroleum Reserve—Alaska.

Respondent's Obligation: Required to Obtain or Retain a Benefit.

Frequency of Collection: On occasion.

Estimated Completion Time per Response: Varies from 15 minutes to 80 hours, depending on activity.

Number of Respondents: 24.

Annual Responses: 24.

Annual Burden Hours: 223.

Annual Burden Cost: $1,320.

If you want to comment on the information-collection requirements in this rule, please send your comments and suggestions on this information-collection request within 30 days of publication of this final rule in the **Federal Register** to OMB at *www.reginfo.gov.* Click on the link, ''Currently under Review—Open for Public Comments.''

J. National Environmental Policy Act

The BLM received comments on this section. One commenter stated the BLM properly issues the rule pursuant to a categorical exclusion. Other comments recommended that the BLM use an environmental assessment for the rule. Commenters stated the rule affects decisions in RMPs, because the preference criteria would guide the BLM's decision making and direct oil and gas leasing to appropriate locations. Another commenter stated that the economic burden that the proposed rule would cause for oil and gas operators and State economies would require the BLM to perform a NEPA analysis on the portions of the proposed rule that are beyond the scope of changes required by Congress in the IRA. As previously stated, this rule does not close additional lands for oil and gas leasing and the MLA has vested the Secretary with broad discretion to decide, up until the time of lease issuance, whether particular parcels of Federal land ''may be leased'' for oil and gas development, see 30 U.S.C. 226(a). The BLM completed an RIA and an extraordinary circumstances review and determined that the BLM can issue this rule under the applicable Departmental categorical exclusion.

A detailed environmental analysis under NEPA is not required, because the final rule is covered by a categorical exclusion (see 43 CFR 46.205). This final rule meets the criteria set forth at 43 CFR 46.210(i) for a Departmental categorical exclusion in that this final rule is ''of an administrative, financial, legal, technical, or procedural nature.'' The BLM also has determined that the final rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

Under E.O. 13211, agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions. This statement is to include a detailed statement of ''any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increase use of foreign supplies)'' for the action and reasonable alternatives and their effects.

Section 4(b) of E.O. 13211 defines a ''significant energy action'' as ''any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under E.O. 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by OIRA as a significant energy action.''

The BLM believes that the final rule may affect the locations that operators choose for future oil or gas development but will have little impact on an entity's decision to invest in energy development, the size of that development, or the production from that development. As a result of this rule, an entity holding existing nonproducing leases may choose to shift more future development to those existing leases or to develop non-Federal acreage instead of securing new Federal leases, and some entities may be relatively less likely to choose a new Federal lease to a comparable non-Federal lease. Also, any incremental changes in oil or gas production estimated to result from the rule's enactment would constitute a small fraction of total U.S. gas production, and any potential and temporary deferred production of oil would likewise constitute a small fraction of total U.S. oil production. Some commenters disagreed and pointed to the preference criteria as increasing the risk for litigation, which could shift development off Federal land and increase the cost to produce gas or oil. The BLM disagrees. The preference criteria under § 3120.32 support the BLM's existing policy and direction to make a public interest determination, which has existed at least since 1988. *See* 53 FR 22828 (June 17, 1988) (''It is Bureau policy prior to offering the lands to determine whether leasing will be in the public interest and to identify stipulation requirements, obtain surface management agency leasing recommendations and consent where applicable and required by law''). It will not have the impact stated in these comments. For these reasons, we do not

expect that the final rule will significantly impact the supply, distribution, or use of energy. As such, the rulemaking is not a ''significant energy action'' as defined in E.O. 13211.

VI. Authors

The principal authors of this final rule include: Peter Cowan, Senior Mineral Leasing Specialist in BLM Headquarters; Jennifer Spencer, Mineral Leasing Specialist in BLM Headquarters; William Lambert, Petroleum Engineer in BLM Headquarters; Natalie Eades, Attorney Advisor in DOI Office of the Solicitor. Technical support provided by: Scott Rickard, Economist in BLM Headquarters; Travis Kern, Program Analyst in BLM Headquarters; and Erik Vernon, Air Resources Program Lead in BLM Utah State Office. Assisted by: Duane Spencer, Deputy State Director of Minerals and Land in BLM Wyoming State Office; JulieAnn Serrano, Supervisory Land Law Examiner in BLM New Mexico State Office; and Darrin King, Senior Regulatory Analyst in BLM Headquarters.

List of Subjects

43 CFR Part 3000

Public lands-mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3100

Government contracts, Mineral royalties, Oil and gas reserves, Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3110

Government contracts, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3120

Government contracts, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3130

Alaska, Government contracts, Mineral royalties, Oil and gas exploration, Oil and gas reserves, Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3140

Government contracts, Hydrocarbons, Mineral royalties, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3150

Administrative practice and procedure, Alaska, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3160

Administrative practice and procedure, Government contracts, Indians-lands, Mineral royalties, Oil and gas exploration, Penalties, Public lands-mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3170

Administrative practice and procedure, Flaring, Immediate assessments, Indians-lands, Mineral royalties, Oil and gas exploration, Oil and gas measurement, Public lands-mineral resources, Reporting and record keeping requirements, Royalty-free use, Venting.

43 CFR Part 3180

Government contracts, Mineral royalties, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Bureau of Land Management amends 43 CFR parts 3000, 3100, 3110, 3120, 3130, 3140, 3150, 3160, 3170, and 3180 as follows:

■ 1. Revise part 3000 to read as follows:

PART 3000—MINERALS MANAGEMENT: GENERAL

Sec.

PART 3000—MINERALS MANAGEMENT: GENERAL

Authority: 16 U.S.C. 3101 *et seq.;* 30 U.S.C. 181 *et seq.,* 301–306, 351–359, and 601 *et seq.;* 31 U.S.C. 9701; 40 U.S.C. 471 *et seq.;* 42 U.S.C. 6508; 43 U.S.C. 1701 *et seq.;* and Pub. L. 97–35, 95 Stat. 357.

§ 3000.5 Definitions.

As used in 43 CFR parts 3000 and 3100, the term:

Acquired lands means lands which the United States obtained by deed through purchase or gift, or through condemnation proceedings, including lands previously disposed of under the public land laws including the mining laws.

Acreage for which expressions of interest have been submitted means acreage that is identified in an expression of interest received by the BLM, that has not been proposed for leasing in any pending sale or other expression of interest pending BLM disposition, and for which the BLM may lawfully issue an oil and gas lease.

Acres offered for lease means all acres that the BLM has offered for oil and gas lease, regardless of whether those acres are acreage for which expressions of interest have been submitted.

Act or *MLA* means the Mineral Leasing Act of 1920, as amended and supplemented (30 U.S.C. 181 *et seq.*).

Anniversary date means the same day and month in succeeding years as that on which the lease became effective.

Authorized officer means any BLM employee authorized to perform the duties described in parts 3000 and 3100.

BLM or *Bureau* means the Bureau of Land Management.

Director means the Director of the Bureau of Land Management.

Gas means any fluid, either combustible or noncombustible, which is produced in a natural state from the earth and which maintains a gaseous or rarefied state at ordinary temperatures and pressure conditions.

Interest means ownership in a lease, or prospective lease, of all or a portion of the record title, working interest, operating rights, overriding royalty, payments out of production, carried interests, net profit share or similar instrument for participation in the benefit derived from a lease. An *interest* may be created by direct or indirect ownership, including options. *Interest* does not mean stock ownership, stockholding or stock control in an application, offer, competitive bid or lease, except for purposes of acreage limitations in 43 CFR 3101.20 and qualifications of lessees in 43 CFR subpart 3102.

Oil means all nongaseous hydrocarbon substances other than those substances leasable as coal, oil shale or gilsonite (including all vein-type solid hydrocarbons).

ONRR means the Office of Natural Resources Revenue.

Party in interest means a party who is or will be vested with any interest under

the lease as defined in this section. No one is a sole party in interest with respect to an application, offer, competitive bid or lease in which any other party has an interest.

Person means any individual, firm, corporation, association, partnership, consortium, or joint venture.

Proper BLM office means the Bureau of Land Management state office having jurisdiction over the lands subject to the regulations in parts 3000 and 3100.

(See 43 CFR 1821.10 for office location and area of jurisdiction of Bureau of Land Management offices.)

Properly filed means a document or form submitted to the proper BLM office with all necessary information and payments, as provided in 43 CFR subpart 1822.

Public domain lands means lands, including mineral estates, which never left the ownership of the United States, lands which were obtained by the United States in exchange for public domain lands, lands which have reverted to the ownership of the United States through the operation of the public land laws and other lands specifically identified by the Congress as part of the public domain.

Secretary means the Secretary of the Interior.

Surface managing agency means any Federal agency, other than the BLM, having management responsibility for the surface resources that overlay federally owned minerals.

§ 3000.10 Nondiscrimination.

Any person acquiring a lease under this chapter must comply fully with the equal opportunity provisions of Executive Order 11246 dated September 24, 1965, as amended, and the rules, regulations and relevant orders of the Secretary of Labor (41 CFR part 60 and 43 CFR part 17).

§ 3000.20 False statements.

As provided in 18 U.S.C. 1001, it is a crime punishable by imprisonment or a fine, or both, for any person knowingly and willfully to submit or cause to be submitted to any agency of the United States any false or fraudulent statement(s) as to any matter within the agency's jurisdiction.

§ 3000.30 Unlawful interests.

No member of, or delegate to, Congress, or Resident Commissioner, and no employee of the Department of the Interior, except as provided in 43 CFR part 20, is allowed or entitled to acquire or hold any Federal lease, or interest therein. (Officer, agent or employee of the Department—see 43 CFR part 20; Member of Congress—see R.S. 3741; 41 U.S.C. 22; 18 U.S.C. 431–433.)

§ 3000.40 Appeals.

Except as provided in 43 CFR 3000.120, 3101.53(b), 3103.1, 3165.4, and 3427.2, any party adversely affected by a decision of the authorized officer made pursuant to the provisions of 43 CFR parts 3000 or 3100 has a right of appeal pursuant to 43 CFR part 4.

§ 3000.41 Severability.

If a court holds any section or its paragraphs of the regulations in parts 3000 through 3180 or their applicability to any person or circumstance invalid, the remainder of these rules and their applicability to other persons or circumstances will not be affected.

§ 3000.50 Limitations on time to institute suit to challenge a decision of the Secretary.

No action challenging a decision of the Secretary involving any oil or gas lease (including decisions on offers or applications to lease) can be maintained unless such action is commenced or taken within 90 days after the final decision of the Secretary relating to such matter.

§ 3000.60 Filing of documents.

All necessary documents must be filed in the proper BLM office. Documents may be submitted to the BLM using hard-copy delivery services, in-person delivery, or by electronic filing. When using hard-copy delivery services or in-person delivery, the document will be considered filed only when received during regular business hours in the proper BLM office. See 43 CFR part 1820, subpart 1822.

§ 3000.70 Multiple development.

The granting of a permit or lease for the prospecting, development or production of deposits of any one mineral does not preclude the issuance of other permits or leases for the same lands for deposits of other minerals with suitable stipulations for simultaneous operation, nor the allowance of applicable entries, locations or selections of leased lands with a reservation of the mineral deposits to the United States.

§ 3000.80 Management of Federal minerals from reserved mineral estates.

Where nonmineral public land disposal statutes provide that in conveyances of title all or certain minerals are reserved to the United States together with the right to prospect for, mine and remove the minerals under applicable law and regulations as the Secretary may prescribe, the lease or sale, and administration and management of the use of such minerals will be accomplished under the regulations of 43 CFR parts 3000 and 3100. Such mineral estates include, but are not limited to, those that have been or will be reserved under the authorities of the Small Tract Act of June 1, 1938, as amended (43 U.S.C. 682(b)) and the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*).

§ 3000.90 Enforcement actions under the United States Code.

The United States Department of Justice is the agency responsible for the enforcement actions described in 30 U.S.C. 195, which makes it unlawful for any person to organize or participate in any scheme, arrangement, plan, or agreement to circumvent or defeat the provisions of the MLA or its implementing regulations; or to seek to obtain or to obtain any money or property by means of false statements of material facts or by failing to state materials facts concerning the:

(a) Value of any lease or portion thereof issued or to be issued under the MLA;

(b) Availability of any land for leasing under the MLA;

(c) Ability of any person to obtain leases under the MLA; or

(d) Provisions of the MLA and its implementing regulations.

§ 3000.100 Fees in general.

(a) *Setting fees.* Fees may be statutorily set fees, relatively nominal filing fees, or processing fees intended to reimburse the BLM for its reasonable processing costs. For processing fees, the BLM takes into account the factors in section 304(b) of the Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1734(b)) before deciding a fee. The BLM considers the factors for each type of document when the processing fee is a fixed fee and for each individual document when the fee is decided on a case-by-case basis, as explained in *§ 3000.*110.

(b) *Conditions for filing.* The BLM will not accept a document that the applicant submits without the proper filing or processing fee amounts except for documents where the BLM sets the fee on a case-by-case basis. Fees are not refundable except as provided for case-by-case fees in *§ 3000.*110. The BLM will keep the fixed filing or processing fee as a service charge even if the BLM does not approve the application or the applicant withdraws it completely or partially.

(c) *Periodic adjustment.* The BLM will periodically adjust fees established in this subchapter according to changes in

the Implicit Price Deflator for Gross Domestic Product, which is published quarterly by the U.S. Department of Commerce. Because the fee recalculations are simply based on a mathematical formula, the BLM will change the fees in final rules without opportunity for notice and comment.

(d) *Timing of fee applicability.* (1) For a document that the BLM received before June 22, 2024, the BLM will not charge a fixed fee or a case-by-case fee under this subchapter for processing that document, except for fees applicable under then-existing regulations.

(2) For a document that the BLM receives on or after June 22, 2024, the applicant must include the required fixed fees with the documents filed, as provided in § 3000.120(a) of this chapter, and the applicant is subject to case-by-case processing fees as provided in § 3000.110 and under other provisions of this chapter.

§ 3000.110 Processing fees on a case-by-case basis.

(a) Fees in this subchapter are designated either as case-by-case fees or as fixed fees. The fixed fees are established in this subchapter for specified types of documents. However, if the BLM decides at any time that a particular document designated for a fixed fee will have a unique processing cost, such as the preparation of an Environmental Impact Statement, the BLM may set the fee under the case-by-case procedures in this section.

(b) For case-by-case fees, the BLM measures the ongoing processing cost for each individual document and considers the factors in section 304(b) of FLPMA on a case-by-case basis according to the following procedures:

(1) The applicant may request the BLM's approval to do all or part of any study or other activity according to standards the BLM specifies, thereby reducing the BLM's costs for processing the document, in accordance with all other applicable laws and regulations.

(2) Before performing any case processing, the BLM will give the applicant a written estimate of the proposed fee for reasonable processing costs after the BLM considers the FLPMA section 304(b) factors.

(3) The applicant may comment on the proposed fee.

(4) The BLM will then give the applicant the final estimate of the processing fee amount after considering the applicant's comments and any BLM-approved work that the applicant will do.

(i) If the BLM encounters higher or lower processing costs than anticipated, the BLM will re-estimate the reasonable processing costs following the procedure in *paragraphs (b)(1) through (4)* of this section, but the BLM will not stop ongoing processing unless the applicant does not pay in accordance with *paragraph (b)(5)* of this section.

(ii) If the fee the applicant would pay under this *paragraph (b)(4)* is less than the BLM's actual costs as a result of consideration of the FLPMA section 304(b) factors, and the BLM is not able to process the document promptly because of the unavailability of funding or other resources, the applicant will have the option to pay the BLM's actual costs to process the document.

(iii) Once processing is complete, the BLM will refund to the applicant any money that the BLM did not spend on processing costs.

(5)(i) The BLM will periodically estimate what its reasonable processing costs will be for a specific period and will bill the applicant for that period. Payment is due to the BLM 30 days after the applicant receives its bill. The BLM will stop processing the document if the applicant does not pay the bill by the date payment is due.

(ii) If a periodic payment turns out to be more or less than the BLM's reasonable processing costs for the period, the BLM will adjust the next billing accordingly or make a refund. Do not deduct any amount from a payment without the BLM's prior written approval.

(6) The applicant must pay the entire fee before the BLM will issue the final document.

(7) The applicant may appeal the BLM's estimated processing costs in accordance with the regulations in 43 CFR part 4, subpart E. The applicant may also appeal any determination the BLM makes under *paragraph (a)* of this section that a document designated for a fixed fee will be processed as a case-by-case fee. The BLM will not process the document further until the appeal is resolved, in accordance with *paragraph (b)(5)(i)* of this section, unless the applicant pays the fee under protest while the appeal is pending. If the appeal results in a decision changing the proposed fee, the BLM will adjust the fee in accordance with *paragraph (b)(5)(ii)* of this section.

§ 3000.120 Fee schedule for fixed fees.

(a) The table in this section lists the services that require payment of fixed fees to the BLM. The fixed fee amounts are posted on the BLM website (*https://www.blm.gov*) and published in a **Federal Register** notice. These fees are nonrefundable and must be included with documents filed under this chapter. Fees will be adjusted annually according to the change in the Implicit Price Deflator for Gross Domestic Product since the previous adjustment and will subsequently be posted on the BLM website (*https://www.blm.gov*) and announced annually in the **Federal Register** before October 1 each year. Revised fees are effective each year on October 1.

TABLE 1 TO PARAGRAPH (a)—PROCESSING AND FILING FEE TABLE

Document/action
Oil & Gas (parts 3100, 3110, 3120, 3130, 3150, 3160, and 3180):
Competitive lease application
Leasing and compensatory royalty agreements under right-of-way pursuant to subpart 3109.
Lease consolidation
Assignment and transfer of record title or operating rights
Overriding royalty transfer, payment out of production
Name change; corporate merger; sheriff's deed; dissolution of corporation, partnership, or trust; or transfer to heir/devisee
Lease reinstatement, Class I
Geophysical exploration permit application—all states
Renewal of exploration permit—Alaska
Final application for Federal unit agreement approval, Federal unit agreement expansion, and Federal subsurface gas storage application
Designation of successor operator for all Federal agreements, except for contracted unit agreements that contain no Federal lands.
Geothermal (part 3200):
Noncompetitive lease application
Competitive lease application
Assignment and transfer of record title or operating rights

TABLE 1 TO PARAGRAPH (a)—PROCESSING AND FILING FEE TABLE—Continued

Document/action
Name change, corporate merger or transfer to heir/devisee
Lease consolidation
Lease reinstatement
Nomination of lands
plus per acre nomination fee
Site license application
Assignment or transfer of site license
Coal (parts 3400, 3470):
License to mine application
Exploration license application
Lease or lease interest transfer
Leasing of Solid Minerals Other Than Coal and Oil Shale (parts 3500, 3580):
Applications other than those listed below
Prospecting permit application amendment
Extension of prospecting permit
Lease modification or fringe acreage lease
Lease renewal
Assignment, sublease, or transfer of operating rights
Transfer of overriding royalty
Use permit
Shasta and Trinity hardrock mineral lease
Renewal of existing sand and gravel lease in Nevada
Public Law 359; Mining in Powersite Withdrawals: General (part 3730):
Notice of protest of placer mining operations
Mining Law Administration (parts 3800, 3810, 3830, 3860, 3870):
Application to open lands to location
Notice of location *
Amendment of location
Transfer of mining claim/site
Recording an annual FLPMA filing
Deferment of assessment work
Recording a notice of intent to locate mining claims on Stockraising Homestead Act lands
Mineral patent adjudication
Adverse claim
Protest
Oil Shale Management (parts 3900, 3910, 3930):
Exploration license application
Application for assignment or sublease of record title or overriding royalty
Onshore Oil and Gas Operations and Production (parts 3160, 3170):
Application for Permit to Drill

* To record a mining claim or site location, this processing fee along with the initial maintenance fee and the one-time location fee required by statute 43 CFR part 3833 must be paid.

(b) The amount of a fixed fee is not subject to appeal to the Interior Board of Land Appeals pursuant to 43 CFR part 4, subpart E.

■ 2. Revise part 3100 to read as follows:

PART 3100—OIL AND GAS LEASING

Subpart 3100—Oil and Gas Leasing: General

Subpart 3101—Issuance of Leases

Subpart 3102—Qualifications of Lessees

Subpart 3103—Fees, Rentals, and Royalty

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359, and 1751; 43 U.S.C. 1701 *et seq.;* and 42 U.S.C. 15801.

Subpart 3100—Onshore Oil and Gas Leasing: General

§ 3100.3 Authority.

(a)(1) *Public domain.* Oil and gas in public domain lands and lands returned to the public domain under 43 CFR part 2370 are subject to lease under the Mineral Leasing Act of 1920, as amended and supplemented (30 *U.S.C. 181 et seq.*), by acts, including, but not limited to, section 1009 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3148).

(2) *Exceptions.* The following lands are not subject to lease.

(i) Units of the National Park System, including lands withdrawn by section 206 of the Alaska National Interest Lands Conservation Act, except as provided in paragraph (g)(4) of this section;

(ii) Indian reservations;

(iii) Incorporated cities, towns and villages;

(iv) Naval petroleum and oil shale reserves;

(v) Lands north of 68 degrees north latitude and east of the western boundary of the National Petroleum Reserve—Alaska;

(vi) Lands recommended for wilderness allocation by the surface managing agency;

(vii) Lands within the BLM's wilderness study areas;

(viii) Lands designated by Congress as wilderness study areas, except where oil and gas leasing is specifically allowed to continue by the statute designating the study area;

(ix) Lands within areas allocated for wilderness or further planning in Executive Communication 1504, Ninety-Sixth Congress (House Document numbered 96–119), unless such lands are allocated to uses other than wilderness by a land and resource management plan or have been released to uses other than wilderness by an Act of Congress;

(x) Lands within the National Wilderness Preservation System, subject to valid existing rights under section 4(d)(3) of the Wilderness Act (16 U.S.C. 1133) established before midnight, December 31, 1983, unless otherwise provided by law;

(xi) Subject to valid existing rights, lands within the National Wild and Scenic Rivers System and that constitute the bed or bank or are situated within one-quarter mile of the bank of any river designated as a wild river under the Wild and Scenic Rivers Act (16 U.S.C. 1280), lands within the National Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-quarter mile of the bank of certain rivers designated as scenic or recreational, and in some cases, designating legislation may apply a different boundary extent. Lands within the National Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-half mile of the bank of any river designated a wild river by the Alaska National Interest Lands Conservation Act (16 U.S.C. 3148); and

(xii) Wildlife refuge lands, which are those lands embraced in a withdrawal of lands of the United States for the protection of all species of wildlife within a particular area. Sole and complete jurisdiction over such lands for wildlife conservation purposes is vested in the Fish and Wildlife Service even though such lands may be subject to prior rights for other public purposes or, by the terms of the withdrawal order, may be subject to mineral leasing. No expressions of interest covering wildlife refuge lands will be considered for oil and gas leasing, except as provided by applicable law.

(b)(1) *Acquired lands.* Oil and gas in acquired lands are subject to lease under the Mineral Leasing Act for Acquired Lands of August 7, 1947, as amended (30 U.S.C. 351 *et seq.*).

(2) *Exceptions.* The following lands are not subject to lease.

(i) Units of the National Park System, except as provided in paragraph (g)(4) of this section;

(ii) Incorporated cities, towns and villages;

(iii) Naval petroleum and oil shale reserves;

(iv) Tidelands or submerged coastal lands within the continental shelf adjacent or littoral to lands within the jurisdiction of the United States;

(v) Lands acquired by the United States for development of helium, fissionable material deposits or other minerals essential to the defense of the country, except oil, gas and other minerals subject to leasing under the Act;

(vi) Lands reported as excess under the Federal Property and Administrative Services Act of 1949;

(vii) Lands acquired by the United States by foreclosure or otherwise for resale;

(viii) Lands recommended for wilderness allocation by the surface managing agency;

(ix) Lands within the BLM's wilderness study areas;

(x) Lands designated by Congress as wilderness study areas, except where oil and gas leasing is specifically allowed to continue by the statute designating the study area;

(xi) Lands within areas allocated for wilderness or further planning in Executive Communication 1504, Ninety-Sixth Congress (House Document numbered 96–119), unless such lands are allocated to uses other than wilderness by a land and resource management plan or have been released to uses other than wilderness by an Act of Congress;

(xii) Lands within the National Wilderness Preservation System, subject to valid existing rights under section 4(d)(3) of the Wilderness Act (16 U.S.C. 1133) established before midnight, December 31, 1983, unless otherwise provided by law;

(xiii) Subject to valid existing rights, lands within the National Wild and Scenic Rivers System and that constitute the bed or bank or are situated within one-quarter mile of the bank of any river designated as a wild river under the Wild and Scenic Rivers Act (16 U.S.C. 1280), lands within the National Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-quarter mile of the bank of certain rivers designated as scenic or recreational, and in some cases, designating legislation may apply a different boundary extent. Lands within the National Wild and Scenic Rivers System that constitute the bed or bank or are situated within one-half mile of the bank of any river designated a wild river by the Alaska National Interest Lands Conservation Act (16 U.S.C. 3148); and

(xiv) Wildlife refuge lands, which are those lands embraced in a withdrawal of lands of the United States for the protection of all species of wildlife within a particular area. Sole and complete jurisdiction over such lands for wildlife conservation purposes is vested in the Fish and Wildlife Service even though such lands may be subject to prior rights for other public purposes or, by the terms of the withdrawal order, may be subject to mineral leasing. No expressions of interest for wildlife refuge lands will be considered except as provided in applicable law.

(c) National Petroleum Reserve—Alaska is subject to lease under the Department of the Interior Appropriations Act, Fiscal Year 1981 (42 U.S.C. 6508).

(d) Where oil or gas is being drained from lands otherwise unavailable for leasing, there is implied authority in the agency having jurisdiction of those lands to grant authority to the BLM to lease such lands (see *43 U.S.C. 1457;* also Attorney General's Opinion of April 2, 1941 (Vol. 40 Op. Atty. Gen. 41)).

(e) Where lands previously withdrawn or reserved from the public domain are no longer needed by the agency for which the lands were withdrawn or reserved and such lands are retained by the General Services Administration, or where acquired lands are declared as excess to or surplus by the General Services Administration, authority to lease such lands may be transferred to the Department in accordance with the Federal Property and Administrative Services Act of 1949 and the Mineral Leasing Act for Acquired Lands, as amended.

(f) The Act of May 21, 1930 (*30 U.S.C. 301–306*), authorizes the leasing of oil and gas deposits under certain rights-of-way to the owner of the right-of-way or any assignee.

(g)(1) *Certain lands in Nevada.* The Act of May 9, 1942 (56 Stat. 273), as amended by the Act of October 25, 1949 (63 Stat. 886), authorizes leasing on certain lands in Nevada.

(2) *Lands patented to the State of California.* The Act of March 3, 1933 (47 Stat. 1487), as amended by the Act of June 5, 1936 (49 Stat. 1482) and the Act of June 29, 1936 (49 Stat. 2026), authorizes leasing on certain lands patented to the State of California.

(3) *National Forest Service Lands in Minnesota.* The Act of June 30, 1950 (16 U.S.C. 508(b)) authorizes leasing on certain National Forest Service Lands in Minnesota.

(4) *Units of the National Park System.* The Secretary is authorized to permit mineral leasing in the following units of the National Park System if the Secretary finds that such disposition would not have significant adverse effects on the administration of the area and if lease operations can be conducted in a manner that will preserve the scenic, scientific and historic features contributing to public enjoyment of the area, pursuant to the following authorities:

(i) *Lake Mead National Recreation Area*—The Act of October 8, 1964 (16 U.S.C. 460n *et seq.*).

(ii) *Whiskeytown Unit of the Whiskeytown-Shasta-Trinity National Recreation Area*—The Act of November 8, 1965 (79 Stat. 1295; 16 U.S.C. 460q *et seq.*).

(iii) *Ross Lake and Lake Chelan National Recreation Areas*—The Act of October 2, 1968 (82 Stat. 926; 16 U.S.C. 90 *et seq.*).

(iv) *Glen Canyon National Recreation Area*—The Act of October 27, 1972 (86 Stat. 1311; 16 U.S.C. 460dd *et seq.*).

(5) *Shasta and Trinity Units of the Whiskeytown-Shasta-Trinity National Recreation Area.* Section 6 of the Act of November 8, 1965 (Pub. L. 89–336; 79 Stat. 1295), authorizes the Secretary of the Interior to permit the removal of leasable minerals from lands (or interest in lands) within the recreation area under the jurisdiction of the Secretary of Agriculture in accordance with the Mineral Leasing Act of February 25, 1920, as amended (30 U.S.C. 181 *et seq.*), or the Acquired Lands Mineral Leasing Act of August 7, 1947 (30 U.S.C. 351 *et seq.*), if the Secretary finds that such disposition would not have

significant adverse effects on the purpose of the Central Valley project or the administration of the recreation area.

(h) Under the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*), all lands within Recreation and Public Purposes leases and patents are subject to lease under the provisions of this part, subject to such conditions as the Secretary deems appropriate.

(i)(1) Coordination lands are those lands withdrawn or acquired by the United States and made available to the States by cooperative agreements entered into between the Fish and Wildlife Service and the game commissions of the various States, in accordance with the Fish and Wildlife Coordination Act (16 U.S.C. 661), or by long-term leases or agreements between the Department of Agriculture and the game commissions of the various States pursuant to the Bankhead-Jones Farm Tenant Act (50 Stat. 525), as amended, where such lands were subsequently transferred to the Department of the Interior, with the Fish and Wildlife Service as the custodial agency of the United States.

(2) Representatives of the BLM and the Fish and Wildlife Service will, in cooperation with the authorized members of the various State game commissions, confer for the purpose of determining by agreement those coordination lands which will not be subject to oil and gas leasing. Coordination lands not closed to oil and gas leasing may be subject to leasing on the imposition of such stipulations as are agreed upon by the State Game Commission, the Fish and Wildlife Service and the BLM.

(j) No lands within a refuge in Alaska open to leasing will be available until the Fish and Wildlife Service has first completed compatibility determinations.

§ 3100.5 Definitions.

As used in this part, the term:

Actual drilling operations includes not only the physical drilling of a well, but also the testing, completing or equipping of such well for production.

Assignment means a transfer of all or a portion of the lessee's record title interest in a lease.

Bid means an amount of remittance offered as partial compensation for a lease equal to or in excess of the national minimum acceptable bonus bid set by statute or by the Secretary, submitted by a person for a lease parcel in a competitive lease sale. For leases or compensatory royalty agreements issued under 43 CFR subpart 3109, ''bid'' means an amount or percent of royalty or compensatory royalty that the owner or lessee must pay for the extraction of the oil and gas underlying the right-of-way.

Competitive auction means an in-person or internet-based bidding process where leases are offered to the highest bidder.

Exception means (as used for lease stipulations) a limited exemption, for a particular site within the leasehold, to a stipulation.

Lessee means a person holding record title in a lease issued by the United States.

Modification means (as used for lease stipulations) a change to the provisions of a lease stipulation for some or all sites within the leasehold and either temporarily or for the term of the lease.

National Wildlife Refuge System Lands means lands and water, or interests therein, administered by the Secretary as wildlife refuges, areas for the protection and conservation of fish and wildlife that are threatened with extinction; wildlife management areas; or waterfowl production areas.

Oil and gas agreement means an agreement between lessees and the BLM to govern the development and allocation of production for existing leases and unleased lands, including, but not limited to, communitization agreements, compensatory royalty agreements, unit agreements, secondary recovery agreements, and gas storage agreements.

Operating right (working interest) means the interest created out of a lease authorizing the holder of that right to enter upon the leased lands to conduct drilling and related operations, including production of oil or gas from such lands in accordance with the terms of the lease. Operating rights include the obligation to comply with the terms of the original lease, as it applies to the area or horizons for the interest acquired, including the responsibility to plug and abandon all wells that are no longer capable of producing, reclaim the lease site, and remedy environmental problems.

Operating rights owner means a person holding operating rights in a lease issued by the United States. A lessee also may be an operating rights owner if the operating rights in a lease or portion thereof have not been severed from record title.

Operator means any person, including, but not limited to, the lessee or operating rights owner, who has stated in writing to the authorized officer that it is responsible under the terms and conditions of the lease for the operations conducted on the leased lands or a portion thereof.

Primary term of lease subject to section 4(d) of the Act prior to the revision of 1960 (30 U.S.C. 226–1(d)) means all periods of the life of the lease prior to its extension by reason of production of oil and gas in paying quantities; and

Primary term of all other leases means the initial term of the lease, which is 10 years.

Qualified bidder means any person in compliance with the laws and regulations governing a bid.

Qualified lessee means any person in compliance with the laws and regulations governing the BLM issued leases held by that person.

Record title means a lessee's interest in a lease, which includes the obligation to pay rent and the ability to assign and relinquish the lease. Record title includes the obligation to comply with the lease terms, including requirements relating to well operations and abandonment. Overriding royalty and operating rights are severable from record title interests.

Responsible bidder means any person who has not defaulted on the payment of winning bids for BLM-issued oil and gas leases, is capable of fulfilling the requirements of onshore BLM oil and gas leases, and is in compliance with statutes and regulations applicable to oil and gas development or with the terms of a BLM-issued oil and gas lease. The term ''responsible bidder'' does not include persons who bid with no intention of paying a winning bid or persons who default on a winning bid.

Responsible lessee means any person who has not defaulted on previous winning bids, is capable of fulfilling the requirements of onshore Federal oil and gas leases, and is in compliance with statutes applicable to oil and gas development or the terms of a BLM-issued oil and gas lease.

Sublease means a transfer of a non-record title interest in a lease, *i.e.,* a transfer of operating rights is normally a sublease, and a sublease also is a subsidiary arrangement between the lessee (sublessor) and the sublessee, but a sublease does not include a transfer of a purely financial interest, such as overriding royalty interest or payment out of production, nor does it affect the relationship imposed by a lease between the lessee(s) and the United States.

Transfer means any conveyance of an interest in a lease by assignment, sublease or otherwise. This definition includes the terms: *Assignment* and *Sublease.*

Unit operator means the person authorized under the unit agreement approved by the Department of the

Interior to conduct operations within the unit.

Waiver means (as used for lease stipulations) a permanent exemption from a lease stipulation.

§ 3100.9 Information collection.

(a) *Authority:* 44 U.S.C. 3501–3520

(b)(1) *Purpose.* The Paperwork Reduction Act of 1995 generally provides that 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 the collection displays a currently valid Office of Management and Budget (OMB) Control Number. This part displays OMB control numbers assigned to information collection requirements contained in the BLM's regulations at 43 CFR part 3100. This section aids in fulfilling the requirements of the Paperwork Reduction Act to display current OMB Control Numbers for these information collection requirements. Interested persons should consult *https://www.reginfo.gov* for the most current information on these OMB control numbers; including among other things, the justification for the information collection requirements, description of likely respondents, estimated burdens, and current expiration dates.

(2) *Table 1 to Paragraph (b)—OMB control number assigned pursuant to the Paperwork Reduction Act.*

43 CFR part or section	OMB control No.
§§ 3100, 3103.41, 3120, and Subpart 3162	1004–0185
§§ 3106, 3135, and 3216	1004–0034
Part 3130	1004–0196
Subpart 3195	1004–0179
§ 3150	1004–0162
§§ 3160,* 3171, 3176, and 3177	1004–0220
§§ 3172, 3173, 3174, 3175	1004–0137
§§ 3162.3–1, 3178.5, 3178.7, 3178.8, 3178.9 and Subpart 3179*	1004–0211

* Information collection requirements for onshore oil and gas operations are generally accounted for under OMB Control Number 1004–0220; however, information collection requirements pertaining to particular to waste prevention, production subject to royalties, and resource conservation are accounted for under OMB Control Number 1004–0211.

§ 3100.10 Helium.

The ownership of and the right to extract helium from all gas produced from lands leased or otherwise disposed of under the Act have been reserved to the United States.

Drainage

§ 3100.21 Compensation for drainage.

Upon a determination by the authorized officer that lands owned by the United States are being drained of oil or gas by wells drilled on adjacent lands, the authorized officer may execute agreements with the owners of adjacent lands whereby the United States and its lessees will be compensated for such drainage. Such agreements must be made with the consent of any lessee affected by an agreement. Such lands may also be offered for lease in accordance with 43 CFR part 3120.

§ 3100.22 Drilling and production or payment of compensatory royalty.

Where lands in any leases are being drained of their oil or gas content by wells either on a Federal lease issued at a lower rate of royalty or on non-Federal lands, the lessee must both drill and produce all wells necessary to protect the leased lands from drainage. In lieu of drilling necessary wells, the lessee may, with the consent of the authorized officer, pay compensatory royalty in accordance with 43 CFR 3162.2–4.

Options

§ 3100.31 Enforceability.

(a) No option to acquire any interest in a lease is enforceable if entered into for a period of more than 3 years (including any renewal period that may be provided for in the option).

(b) No option or renewal thereof is enforceable until a signed copy or notice of the option has been filed in the proper BLM office. Each such signed copy or notice must include:

(1) The names and addresses of the parties thereto;

(2) The serial number of the lease to which the option is applicable;

(3) A statement of the number of acres and the type and percentage of interests to be conveyed and retained by the parties to the option, including the date and expiration date of the option.

(c) The signatures of all parties to the option or their duly authorized agents. The signed copy or notice of the option required by this paragraph must contain or be accompanied by a signed statement by the holder of the option that entity is the sole party in interest in the option; if not, the entity must set forth the names and provide a description of the interest therein of the other interested parties, and provide a description of the agreement between them, if oral, and a copy of such agreement, if written.

§ 3100.32 Effect of option on acreage.

The acreage to which the option is applicable will be charged both to the grantor of the option and the option holder. The acreage covered by an unexercised option remains charged during its term until notice of its relinquishment or surrender has been filed in the proper BLM office.

§ 3100.33 Option statements.

Each option holder must file in the proper BLM office within 90 days after June 30 and December 31 of each year a statement showing:

(a) Any changes to the statements submitted under § 3100.31(b); and

(b) The number of acres covered by each option and the total acreage of all options held in each State.

§ 3100.40 Public availability of information.

(a) All data and information concerning Federal and Indian minerals submitted under this part 3100 and parts 3120 through 3190 of this chapter are subject to 43 CFR part 2, except as provided in paragraph (c) of this section. 43 CFR part 2 includes the regulations of the Department of the Interior covering the public disclosure of data and information contained in Department of the Interior records. Certain mineral information not protected from public disclosure under 43 CFR part 2 may be made available for inspection without a Freedom of Information Act (FOIA) (5 U.S.C. 552) request.

(b) When you submit data and information under this part 3100 and parts 3120 through 3190 of this chapter that you believe to be exempt from disclosure to the public, you must clearly mark each page that you believe includes confidential information. The BLM will keep all such data and information confidential to the extent allowed by 43 CFR 2.26.

(c) Under the Indian Mineral Development Act of 1982 (IMDA) (25 U.S.C. 2101 *et seq.*), the Department of the Interior will hold as privileged proprietary information of the affected Indian or Indian Tribe—

(1) All findings forming the basis of the Secretary's intent to approve or disapprove any Minerals Agreement under IMDA; and

(2) All projections, studies, data, or other information concerning a Minerals Agreement under IMDA, regardless of the date received, related to:

(i) The terms, conditions, or financial return to the Indian parties;

(ii) The extent, nature, value, or disposition of the Indian mineral resources; or

(iii) The production, products, or proceeds thereof.

(d) For information concerning Indian minerals not covered by paragraph (c) of this section:

(1) The BLM will withhold such records as may be withheld under an exemption to FOIA when it receives a request for information related to tribal or Indian minerals held in trust or subject to restrictions on alienation;

(2) The BLM will notify the Indian mineral owner(s) identified in the records of the Bureau of Indian Affairs (BIA) and give them a reasonable period of time to state objections to disclosure, using the standards and procedures of 43 CFR 2.28, before making a decision about the applicability of FOIA exemption 4 to:

(i) Information obtained from a person outside the United States Government; when

(ii) Following consultation with a submitter under 43 CFR 2.28, the BLM determines that the submitter does not have an interest in withholding the records that can be protected under FOIA; but

(iii) The BLM has reason to believe that disclosure of the information may result in commercial or financial injury to the Indian mineral owner(s) but is uncertain that such is the case.

Subpart 3101—Issuance of Leases

Lease Terms and Conditions

§ 3101.11 Lease form.

A lease will be issued only on the standard form approved by the Director.

§ 3101.12 Surface use rights.

A lessee will have the right to use only so much of the leased lands as is necessary to explore for, drill for, mine, extract, remove and dispose of all the leased resource in a leasehold subject to applicable requirements, including stipulations attached to the lease, restrictions deriving from nondiscretionary statutes, and such reasonable measures as may be required and detailed by the authorized officer to mitigate adverse impacts to other resource values, land uses or users, federally recognized Tribes, and underserved communities. Such reasonable measures may include, but are not limited to, relocation or modification to siting or design of facilities, timing of operations, specification of interim and final reclamation measures, and specification of rates of development and production in the public interest. At a minimum, modifications that are consistent with lease rights include, but are not limited to, requiring relocation of proposed operations by up to 800 meters and prohibiting new surface disturbing operations for a period of up to 90 days in any lease year.

§ 3101.13 Stipulations and information notices.

(a) The BLM may consider the sensitivity and importance of potentially affected resources and any uncertainty concerning the present or future condition of those resources and will assess whether a resource is adequately protected by stipulation while considering the restrictiveness of the stipulation on operations.

(b) The authorized officer may require stipulations as conditions of lease issuance. Stipulations will become part of the lease and will supersede inconsistent provisions of the standard lease form. Any party submitting a bid under part 3120 will be deemed to have agreed to stipulations applicable to the specific parcel as indicated in the Notice of Competitive Lease Sale available from the proper BLM office.

(c) The BLM may attach an information notice to the lease. An information notice has no legal consequences, except to give notice of existing requirements, and may be attached to a lease by the authorized officer at the time of lease issuance to convey certain operational, procedural or administrative requirements relative to lease management within the terms and conditions of the standard lease form. Information notices may not be a basis for denial of lease operations.

(d) Where the surface managing agency is the Fish and Wildlife Service, leases will be issued subject to stipulations prescribed by the Fish and Wildlife Service as to the time, place, nature and condition of such operations in order to minimize impacts to fish and wildlife populations and habitat and other refuge resources on the areas leased. The specific conduct of lease activities on any refuge lands will be subject to site-specific stipulations prescribed by the Fish and Wildlife Service.

§ 3101.14 Modification, waiver, or exception.

(a) If the authorized officer determines that a change to a lease term or stipulation is substantial or a stipulation involves an issue of major concern to the public, except for changes to stipulations governing time of year restrictions (such as those related to protected species) supported by data showing that the restrictions are unnecessary, the changes will be subject to public review for at least 30 calendar days.

(b) Prior to lease issuance, if the BLM determines that an additional stipulation will be added to the lease or a modification to an existing stipulation is required, the potential lessee must be given an opportunity to accept the additional or modified stipulation. If the potential lessee does not accept the additional or modified stipulation, the BLM may reject the bid, and may include the lands in the next Notice of Competitive Lease Sale. If the change in stipulation(s) increases the value of the parcel, the BLM will reject the bid, and will include the lands in the next Notice of Competitive Lease Sale.

(c) After lease issuance, if a lessee does not accept an additional or modified stipulation, that additional or modified stipulation is not binding on the lessee and is without effect. When a stipulation is required by the relevant Resource Management Plan, or surface management agency land management plan, and was inadvertently omitted, a lessee's failure to sign and accept changes in the stipulations when requested by the authorized officer may subject the lease to cancellation.

(d) A stipulation included in an oil and gas lease will be subject to modification, waiver, or exception if the authorized officer determines, in conjunction with the applicable surface management agency, that the factors leading to its inclusion in the lease have changed sufficiently to make the specific protections provided by the stipulation no longer justified.

Acreage Limitations

§ 3101.21 Public domain lands.

(a) No person may take, hold, own or control more than 246,080 acres of Federal oil and gas leases on public domain lands in any one State at any one time. No more than 200,000 acres of such acres may be held under option.

(b) In Alaska, the acreage that can be taken, held, owned or controlled is limited to 300,000 acres in the northern leasing district and 300,000 acres in the southern leasing district, of which no more than 200,000 acres may be held under option in each of the two leasing districts. The boundary between the two leasing districts in Alaska begins at the northeast corner of the Tetlin National Wildlife Refuge as established by section 302(8) of the Alaska National Interest Lands Conservation Act, at a point on the boundary between the United States and Canada, then northwesterly along the northern boundary of the refuge to the left limit of the Tanana River (63°9′38″ north latitude, 142°20′52″ west longitude), then westerly along the left limit to the confluence of the Tanana and Yukon Rivers, and then along the left limit of

the Yukon River from said confluence to its principal southern mouth.

§ 3101.22 Acquired lands.

Separate from, and in addition to, the limitation for public domain lands, no person may take, hold, own or control more than 246,080 acres of Federal oil and gas leases on acquired lands in any one State at any one time. No more than 200,000 acres of such acres may be held under option. Where the United States owns only a fractional interest in the mineral resources of the lands involved in a lease, only that part owned by the United States will be charged as acreage holdings. The acreage embraced in a future interest lease will not be charged as acreage holdings until the lease for the future interest becomes effective.

§ 3101.23 Excepted acreage.

(a) The following acreage will not be included in computing acreage limitations:

(1) Acreage under any lease any portion of which is committed to any federally approved oil and gas agreement;

(2) Acreage under any lease for which royalty (including compensatory royalty or royalty in-kind) was paid in the preceding calendar year; and

(3) Acreage under leases subject to an operating, drilling or development contract approved by the Secretary, as provided in 43 CFR 3105.30.

(b) Acreage subject to offers to lease, overriding royalties and payments out of production will not be included in computing acreage limitations.

§ 3101.24 Excess acreage.

(a) Where, as the result of the termination or contraction of an oil and gas agreement or the elimination of a lease from an operating, drilling, or development contract, a party holds or controls excess accountable acreage, that party will have 90 calendar days from the date of termination, contraction or elimination, to reduce the holdings to the prescribed limitation and to file proof of the reduction in the proper BLM office. Where, as a result of a merger or the purchase of the controlling interest in a corporation, a party acquired acreage in excess of the amount permitted, the party holding the excess acreage will have 180 calendar days from the date of the merger or purchase to divest the excess acreage. If additional time is required to complete the divestiture of the excess acreage, a petition requesting additional time, along with a full justification for the additional time, may be filed with the authorized officer prior to the termination of the 180 days provided herein.

(b) If any person is found to hold accountable acreage in violation of the provisions of these regulations, lease(s) or interests therein will be subject to cancellation or forfeiture in their entirety, until sufficient acreage has been eliminated to comply with the acreage limitation. Excess acreage or interest will be cancelled in the inverse order of acquisition.

§ 3101.25 Computation.

The accountable acreage of a party owning an undivided interest in a lease will be the party's proportionate part of the total lease acreage.

§ 3101.30 Leases within unit areas, joinder evidence required.

Before issuance of a lease for lands within an approved unit, the lease offeror must file evidence with the proper BLM office that it has joined in the unit agreement and unit operating agreement or a statement giving satisfactory reasons for its failure to enter into such agreement. If such statement is satisfactory to the authorized officer, the lessee may be permitted to operate independently but will be required to conform to the terms and provisions of the unit agreement with respect to such operations.

§ 3101.40 Terminated leases.

(a) The authorized officer will not issue a lease for lands which have been covered by a lease which terminated automatically until 90 calendar days after the date of termination.

(b) The authorized officer will not, after the receipt of a petition for reinstatement, issue a new lease affecting any of the lands covered by the terminated lease until all action on the petition is final.

Federal Lands Administered by an Agency Other Than the Bureau of Land Management

§ 3101.51 General requirements.

Public domain and acquired lands will be leased only after seeking concurrence from the surface managing agency, which, upon receipt of a description of the lands from the authorized officer, may report to the authorized officer that it consents to leasing with stipulations, if any, or withholds consent or objects to leasing.

§ 3101.52 Action by the Bureau of Land Management.

(a) Where the surface managing agency has consented to leasing with required stipulations, and the Secretary decides to issue a lease, the authorized officer will incorporate the stipulations into any lease which it may issue. The authorized officer may add other appropriate stipulations.

(b) The authorized officer will not issue a lease on lands to which the surface managing agency objects or withholds consent and for which consent or concurrence is required by law.

(c) The authorized officer will review all recommendations of the surface managing agency and will accept all reasonable recommendations.

(d) Where the surface managing agency is the Fish and Wildlife Service, there will be no drilling or prospecting under any lease heretofore or hereafter issued on lands within a wildlife refuge, except with the consent and approval of the Secretary with the concurrence of the Fish and Wildlife Service as to the time, place and nature of such operations in order to give complete protection to wildlife populations and wildlife habitat on the areas leased, and all such operations must be conducted in accordance with BLM stipulations.

§ 3101.53 Appeals.

(a) The decision of the authorized officer to reject an offer to lease or to issue a lease with stipulations recommended by the surface managing agency may be appealed to the Interior Board of Land Appeals under 43 CFR part 4.

(b) Where, as provided by statute, the surface managing agency has required that certain stipulations be included in a lease or has consented, or objected or refused to consent to leasing, any appeal by an affected lease offeror will be subject to the administrative remedies if provided for by the particular surface managing agency.

§ 3101.60 State's or charitable organization's ownership of surface overlying federally owned minerals.

Where the United States has conveyed title to, or otherwise transferred the control of the surface of lands to any State or political subdivision, agency, or instrumentality thereof, or a college or any other educational corporation or association, or a charitable or religious corporation or association, with reservation of the oil and gas rights to the United States, such party will be given an opportunity to suggest any lease stipulations deemed necessary for the protection of existing surface improvements or uses, to set forth the facts supporting the necessity of the stipulations and also to file any objections it may have to the issuance of a lease. Where a party controlling the surface opposes the issuance of a lease

or wishes to place such restrictive stipulations upon the lease that it could not be operated upon or become part of a drilling unit and hence is without mineral value, the facts submitted in support of the opposition or request for restrictive stipulations may be given consideration and each case will be decided on its merits. The opposition to lease or necessity for restrictive stipulations expressed by the party controlling the surface affords no legal basis or authority to refuse to issue the lease or to issue the lease with the requested restrictive stipulations for the reserved minerals in the lands; in such case, the final determination whether to issue and with what stipulations, or not to issue the lease depends upon whether or not the interests of the United States would best be served by the issuance of the lease.

Subpart 3102—Qualifications of Lessees

§ 3102.10 Who may hold leases.

Leases or interests therein may be acquired and held only by citizens of the United States; associations (including partnerships and trusts) of such citizens; corporations organized under the laws of the United States or of any State or Territory thereof; and municipalities.

§ 3102.20 Non-U.S. Citizens.

(a) Leases or interests therein may be acquired and held by non-U.S. Citizens only through stock ownership, holding or control in a present or potential lessee that is incorporated under the laws of the United States or of any State or territory thereof, and only if the laws, customs or regulations of their country do not deny similar or like privileges to citizens or corporations of the United States. If it is determined that a country has denied similar or like privileges to citizens or corporations of the United States, it would be placed on a list available from any BLM State office.

(b) The Committee on Foreign Investment in the United States is authorized to review covered real estate transactions and to mitigate any risk to the national security of the United States that arises as a result of such transactions. Covered real estate transactions may include certain transactions involving the Federal mineral estate (see 31 CFR part 802).

§ 3102.30 Minors.

Leases must not be acquired or held by someone considered to be a minor under the laws of the State in which the lands are located, but leases may be acquired and held by legal guardians or trustees of minors on their behalf. Such legal guardians or trustees must be citizens of the United States or otherwise meet the provisions of 43 CFR 3102.10.

§ 3102.40 Signature.

Signatures on all applications and BLM forms certify acceptance of lease terms and stipulations, as well as compliance with the regulations under 43 CFR part 3100. Refer to § 3102.50 for certification of compliance and evidence. The BLM also accepts electronic signatures and submissions.

(a) A bid to lease must be made on a current form approved by the Director. Copies must be exact reproductions of the official approved form, without additions, omissions, or other changes. When the bid is filed in person at the proper BLM office, the bid must be typed or printed plainly, signed, and dated by the offeror or an authorized agent on behalf of the present or potential lessee. Bids may be made to the BLM by other arrangements, such as electronically signed and filed, when specifically authorized by the BLM.

(b) Documents signed by any party other than the present or potential lessee must be rendered in a manner to reveal the name of the present or potential lessee, the name of the signatory and their relationship. A signatory who is a member of the organization that constitutes the present or potential lessee (*e.g.,* officer of a corporation, partner of a partnership, etc.) may be requested by the authorized officer to clarify his/her relationship, when the relationship is not shown on the documents filed.

Compliance, Certification of Compliance and Evidence

§ 3102.51 Compliance.

Only responsible and qualified bidders and lessees may own, hold, or control an interest in a lease or prospective lease. Responsible and qualified bidders and lessees, including corporations, and all members of associations, including partnerships of all types, will, without exception, be qualified and in compliance with the Act. Compliance means that the persons are:

(a) Citizens of the United States (see § 3102.10) or non-U.S. citizens who own stock in a corporation organized under State or Federal law (see § 3102.20);

(b) In compliance with the Federal acreage limitations (see § 3101.20);

(c) Not minors (see § 3102.30);

(d) Except for an assignment or transfer under 43 CFR subpart 3106, in compliance with section 2(a)(2)(A) of the Act (30 U.S.C. 201(2)(A)), in which case the signature on a bid or lease constitutes evidence of compliance. A lease issued to any person in violation of this paragraph (d) will be subject to the cancellation provisions of 43 CFR 3108.30.

(e) Not in violation of the provisions of section 41 of the Act (30 U.S.C. 195); and

(f) In compliance with section 17(g) of the Act (30 U.S.C. 226(g)), in which case the signature on an offer, lease, assignment, or transfer constitutes evidence of compliance that the signatory and any subsidiary, affiliate, or person, association, or corporation controlled by or under common control with the signatory, as defined in 43 CFR 3400.0–5(rr), has not failed or refused to comply with reclamation requirements with respect to all leases and operations thereon in which such person has an interest. A person is noncompliant with section 17(g) of the Act when they fail to comply with their reclamation obligations or other standards established under 30 U.S.C. 226 in the time specified in a notice from the BLM. A lease issued, or an assignment or transfer approved, to any such person in violation of this paragraph (f) may be subject to the cancellation provisions of 43 CFR 3108.30, notwithstanding any administrative or judicial appeals that may be pending with respect to violations or penalties assessed for failure to comply with the prescribed reclamation standards on any lease holdings. Noncompliance will end upon a determination by the authorized officer that all required reclamation has been completed and that the United States has been fully reimbursed for any costs incurred due to the required reclamation.

(g) In compliance with 43 CFR 3106.10(d) and section 30A of the Act (30 U.S.C. 187(a)). The authorized officer may accept the signature on a request for approval of an assignment of less than 640 acres outside of Alaska (2,560 acres within Alaska) as acceptable certification that the assignment would further the development of oil and gas, or the authorized officer may apply the provisions of 43 CFR 3102.53.

(h) Not excluded or disqualified from participating in a transaction covered by Federal non-procurement debarment and suspension (2 CFR parts 180 and 1400), unless the Department explicitly approves an exception for a transaction pursuant to the regulations in those parts.

§ 3102.52 Certification of compliance.

Any party(s) seeking to obtain an interest in a lease must certify that it is

in compliance with the Act as set forth in 43 CFR 3102.51. A corporation or publicly traded association, including a publicly traded partnership, must certify that constituent members of the corporation, association or partnership holding or controlling more than 10 percent of the instruments of ownership of the corporation, association or partnership are in compliance with the Act. Execution and submission of a competitive bid form or request for approval of a transfer of record title or of operating rights (sublease), constitutes certification of compliance.

§ 3102.53 Evidence of compliance.

The authorized officer may request at any time further evidence of compliance and qualification from any party holding or seeking to hold an interest in a lease. Failure to comply with the request of the authorized officer will result in adjudication of the action based on the incomplete submission.

Subpart 3103—Fees, Rentals and Royalty

§ 3103.1 Fiscal terms.

(a) The table in this section shows the fiscal terms, that the BLM will adjust every 4 years by a final rule. The BLM will adjust the amounts according to the change in the Implicit Price Deflator for Gross Domestic Product since the previous adjustment. The fiscal terms displayed below are effective on June 22, 2024. Per the Inflation Reduction Act, the BLM will not adjust the rental nor the minimum bonus bids until after August 16, 2032.

TABLE 1 TO PARAGRAPH (a)—FISCAL TERMS TABLE

Oil and gas (parts 3100, 3110, 3120, 3130, 3140):	Fiscal term
Competitive oil and gas, tar sand, and combined hydrocarbon leases	Rental of $3 per acre, or fraction thereof, per year during the first 2-year period beginning upon lease issuance, $5 per acre per year, or fraction thereof, for the following 6 years, and then $15 per acre, or fraction thereof, per year thereafter.
Competitive lease reinstatement, Class II	Rental of $20 per acre, or fraction thereof.
Competitive combined hydrocarbon leases	Minimum bonus bids of $25 per acre, or fraction thereof.
Competitive oil and gas and tar sand leases	Minimum bonus bids of $10 per acre, or fraction thereof.
Expression of interest filing fee	$5 per acre.

(b) The amounts in the fiscal terms table are not subject to appeal to the Interior Board of Land Appeals pursuant to 43 CFR part 4, subpart E.

Payments

§ 3103.11 Form of remittance.

All remittances must be by personal check, cashier's check, certified check, or money order, and must be made payable to the Department of the Interior—Bureau of Land Management or the Department of the Interior—Office of Natural Resources Revenue, as appropriate. Payments made to the BLM may be made by other arrangements such as by electronic funds transfer or credit card when specifically authorized by the BLM. In the case of payments made to the ONRR, such payments may also be made by electronic funds transfer.

§ 3103.12 Where remittance is submitted.

(a)(1) All processing fees for the respective lease applications, nominations, or requests for approval of a transfer found in the fee schedule in § 3000.120 of this chapter and all first-year rentals and bonuses for leases issued under 43 CFR part 3100 must be paid to the proper BLM office.

(2) All second year and subsequent rentals, except for leases specified in paragraph (b) of this section, must be paid to the ONRR, refer to 30 CFR 1218.51.

(b) All rentals and royalties on producing leases, communitized leases in producing spacing units, unitized leases in producing unit areas, leases on which compensatory royalty is payable and all payments under subsurface storage agreements must be paid to the ONRR.

Rentals

§ 3103.21 Rental requirements.

(a) Each competitive bid submitted in response to a Notice of Competitive Lease Sale must be accompanied by full payment of the first year's rental based on the total acreage for that lease in the Notice of Competitive Lease Sale.

(b) If the acreage is incorrectly indicated in a Notice of Competitive Lease Sale, payment of the rental based on the error is curable within 15 calendar days of receipt of notice from the authorized officer of the error.

(c) Rental will not be prorated for any lands in which the United States owns an undivided fractional interest and must be paid for the full acreage in such lands.

§ 3103.22 Annual rental payments.

Rentals must be paid on or before the lease anniversary date. A full year's rental must be submitted even when less than a full year remains in the lease term, except as provided in 43 CFR 3103.42(d). Failure to make the required payment on or before the lease anniversary date will cause a lease to terminate automatically by operation of law. If the designated ONRR office is not open on the anniversary date, payment received on the next day the designated ONRR office is open to the public will be deemed to be timely made. Payments made to an improper BLM or ONRR office will be returned and will not be forwarded to the designated ONRR office. Rental must be paid at the following rates:

(a) The annual rental for all leases is as stated in the lease, and the annual rental for all new leases will be as specified in 43 CFR 3103.1;

(b) Rental will not be due on acreage for which royalty or minimum royalty is being paid, except on nonproducing leases when compensatory royalty has been assessed in which case annual rental as established in the lease will be due in addition to compensatory royalty;

(c) For leases that are reinstated under § 3108.23, the annual rental will be as specified in 43 CFR 3103.1 beginning with the termination date upon the filing of a petition to reinstate a lease; and

(d) Each succeeding time a specific lease is reinstated under § 3108.23, the annual rental on that lease will increase by an additional $10 per acre or fraction thereof.

Royalties

§ 3103.31 Royalty on production.

(a) Royalty on production will be payable only on the mineral interest owned by the United States. Royalty must be paid in the amount or value of the production removed or sold as follows:

(1) For leases issued before August 16, 2022, the rate prescribed in the lease or in applicable regulations at the time of lease issuance;

(2) For leases issued between August 16, 2022, and August 16, 2032, the royalty rate will be 16.67 percent;

(3) For leases issued on or after August 16, 2032, a rate of not less than 16.67 percent on all leases issued under the Act;

(4) A minimum of 16.67 percent on all leases issued under 43 CFR subpart 3109;

(5) For reinstated leases, the rate used for royalty determination that applies to new leases at the time of the reinstatement plus 4 percentage points, plus an additional 2 percentage points for each succeeding reinstatement. In no case will royalties on the reinstated lease be less than 20 percent.

(b) Leases that qualify under specific provisions of the Act of August 8, 1946 (30 U.S.C. 226c) may apply for a limitation of a 12½ percent royalty rate.

(c) The average production per well per day for oil and gas will be determined pursuant to 43 CFR 3162.7–4.

(d) Payment of a royalty on the helium component of gas will not convey the right to extract the helium from the gas stream. Applications for the right to extract helium from the gas stream will be made under 43 CFR part 16.

§ 3103.32 Minimum royalties.

(a) A minimum royalty must be paid at the expiration of each lease year beginning on or after a discovery of oil or gas in paying quantities on the lands leased, except on unitized leases that lack production, the minimum royalty must be paid only on the participating acreage, at the following rates:

(1) On leases issued on or after August 8, 1946, and on those issued prior thereto if the lessee files an election under section 15 of the Act of August 8, 1946, a minimum royalty of $1 per acre or fraction thereof in lieu of rental, except as provided in paragraph (a)(2) of this section; and

(2) On leases issued from offers filed after December 22, 1987, and on competitive leases issued after December 22, 1987, a minimum royalty in lieu of rental of not less than the amount of rental which otherwise would be required for that lease year.

(b) Minimum royalties will not be prorated for any lands in which the United States owns a fractional interest and must be paid on the full acreage of the lease.

(c) Minimum royalties and rentals on non-participating acreage must be paid to the ONRR.

(d) The minimum royalty provisions of this section are applicable to leases reinstated under 43 CFR 3108.23.

(e) If the royalty paid during any year aggregates to less than the minimum royalty, then the lessee must pay the difference at the end of the lease year.

Production Incentives

§ 3103.41 Royalty reductions.

(a) In order to encourage the greatest ultimate recovery of oil or gas and in the interest of conservation, the Secretary, upon a determination that it is necessary to promote development or that the leases cannot be produced in paying quantities under the terms provided therein, may waive, suspend or reduce the rental or minimum royalty or reduce the royalty on an entire leasehold, or any portion thereof.

(b)(1) An application for the benefits under paragraph (a) of this section must be filed by the operator/payor in the proper BLM office. The application must contain the serial number of the leases, the names of the record title holders, operating rights owners (sublessees), and operators for each lease, the description of lands by legal subdivision and a description of the relief requested.

(2) Each application must show the number, location and status of each well drilled, a tabulated statement for each month covering a period of not less than 6 months prior to the date of filing the application of the aggregate amount of oil or gas subject to royalty, the number of wells counted as producing each month and the average production per well per day.

(3) Every application must contain a detailed statement of expenses and costs of operating the entire lease, the income from the sale of any production and all facts tending to show whether the wells can be produced in paying quantities upon the fixed royalty or rental. Where the application is for a reduction in royalty, complete information must be furnished as to whether overriding royalties, payments out of production, or similar interests are paid to others than the United States, the amounts so paid and efforts made to reduce them. The applicant must also file agreements of the holders to a reduction of all other royalties or similar payments from the leasehold to an aggregate not in excess of one-half the royalties due the United States.

(c) Petition may be made for a reduction of royalty for leases reinstated under 43 CFR 3108.23. Petitions to waive, suspend or reduce rental or minimum royalty for leases reinstated under 43 CFR 3108.23 may be made under this section.

§ 3103.42 Suspension of operations and/or production.

(a) A suspension of all operations and production may be directed or consented to by the authorized officer only in the interest of conservation of natural resources. A suspension of operations only or a suspension of production only may be directed or consented to by the authorized officer in cases where the lessee is prevented from operating on the lease or producing from the lease, despite the exercise of due care and diligence, by reason of *force majeure,* that is, by matters beyond the reasonable control of the lessee. Applications for any suspension must be filed in the proper BLM office. Complete information showing the necessity of such relief must be furnished.

(b) The term of any lease will be adjusted to account for the suspension. Beginning on the date the suspension is lifted, the term will be extended by the time that was remaining on the term of the lease on the effective date of the suspension. No lease will expire during any suspension.

(c) A suspension will take effect as of the time specified in the direction or assent of the authorized officer, in accordance with the provisions of 43 CFR 3165.1.

(d) Rental and minimum royalty payments will be suspended during any period of suspension of all operations and production directed or assented to by the authorized officer beginning with the first day of the lease month in which the suspension of all operations and production becomes effective, or if the suspension of all operations and production becomes effective on any date other than the first day of a lease month, beginning with the first day of

the lease month following such effective date. However, if there is any production sold or removed during the suspension, the lessee must pay royalty on that production.

(e) Rental and minimum royalty payments will resume on the first day of the lease month in which the suspension of all operations and production is lifted. Where rentals are creditable against royalties and have been paid in advance, proper credit may be allowed on the next rental or royalty due under the terms of the lease.

(f) Rental and minimum royalty payments will not be suspended during any period of suspension of operations only or suspension of production only.

(g) Where all operations and production are suspended on a lease on which there is a well capable of producing in paying quantities and the authorized officer approves resumption of operations and production, such resumption will be regarded as lifting the suspension, including the suspension of rental and minimum royalty payments, as provided in paragraph (e) of this section.

(h) The relief authorized under this section also may be obtained for any Federal lease included within an approved oil and gas agreement. Oil and gas agreement obligations will not be suspended by relief obtained under this section but will be suspended only in accordance with the terms and conditions of the specific agreement.

Subpart 3104—Bonds

§ 3104.1 Bond amounts.

(a) The table in this section shows the minimum bond amounts, that the BLM will adjust every 10 years by a final rule. The BLM will adjust the amounts according to the change in the Implicit Price Deflator for Gross Domestic Product since the previous adjustment. The minimum bond amounts displayed below are effective on June 22, 2024.

TABLE 1 TO PARAGRAPH (a)—MINIMUM BOND AMOUNT TABLE

Oil and gas (parts 3100, 3110, 3120, 3130, 3140):	Minimum bond amount
Lease Bond	$150,000
Statewide Bond	500,000

(b) The Minimum Bond Amount are not subject to appeal to the Interior Board of Land Appeals pursuant to 43 CFR part 4, subpart E.

(c) Principals must increase or replace all bonds not meeting the appropriate minimum bond amount in paragraph (a) by:

(1) June 22, 2026, for statewide; and

(2) June 22, 2027, for lease bonds.

(d) Failure to increase or replace an existing bond that does not meet the minimum bond amount may:

(1) Subject all wells covered by the bond(s) to shut down under the provisions of 43 CFR 3163.1(a)(3);

(2) Subject all leases covered by the bond(s) to cancellation under the provisions of 43 CFR 3108.30; and

(3) Result in the BLM referring the bond obligor or principal to the Department's Suspension and Debarment Program under 2 CFR part 1400 to determine if the person will be suspended or debarred from doing business with the Federal Government.

§ 3104.10 Bond obligations.

(a) Prior to the commencement of surface disturbing activities related to drilling operations, the lessee, operating rights owner (sublessee), or operator must submit a surety or a personal bond, conditioned upon compliance with all of the terms and conditions of the entire leasehold(s) covered by the bond, as described in this subpart. The bond amounts must be not less than the minimum amounts described in this subpart in order to ensure compliance with the Act, including complete and timely plugging of the well(s), reclamation of the lease area(s), and the restoration of any lands or surface waters adversely affected by lease operations after the abandonment or cessation of oil and gas operations on the lease(s) in accordance with, but not limited to, the standards and requirements set forth in 43 CFR 3162.3 and 3162.5 and orders issued by the authorized officer.

(b) Surety bonds must be issued by qualified surety companies approved by the Department of the Treasury (see Department of the Treasury Circular No. 570).

(c) Personal bonds must be accompanied by a:

(1) Certificate of deposit issued by a financial institution, the deposits of which are federally insured, explicitly granting the Secretary full authority to demand immediate payment in case of default in the performance of the terms and conditions of the lease. The certificate will explicitly indicate on its face, or through assignment, that Secretarial approval is required prior to redemption of the certificate of deposit by any party;

(2) Cashier's check;

(3) Certified check; or

(4) Negotiable Treasury securities of the United States of a value equal to the amount specified in the bond. Negotiable Treasury securities must be accompanied by a proper conveyance to the Secretary of full authority to sell such securities in case of default in the performance of the terms and conditions of a lease.

(5) Irrevocable letter of credit issued by a financial institution, for a specific term, identifying the secretary as sole payee with full authority to demand immediate payment in the case of default in the performance of the terms and conditions of a lease. Letters of credit must be subject to the following conditions:

(i) The letter of credit must be issued only by a financial institution organized or authorized to do business in the United States;

(ii) The letter of credit must be irrevocable during its term. A letter of credit used as security for any lease upon which drilling has taken place and final approval of all abandonment has not been given, or as security for an individual lease or statewide bond, will be forfeited and will be collected by the authorized officer if not replaced by other suitable bond or letter of credit at least 30 days before its expiration date;

(iii) The letter of credit must be payable to the Bureau of Land Management upon demand, in part or in full, upon receipt from the authorized officer of a notice of collection stating the basis therefore, *e.g.,* default in compliance with the lease terms and conditions or failure to file a replacement in accordance with paragraph (c)(5)(ii) of this section;

(iv) The initial expiration date of the letter of credit must be at least 1 year following the date it is filed in the proper BLM office; and

(v) The letter of credit must contain a provision for automatic renewal for periods of not less than 1 year in the absence of notice to the proper BLM office at least 90 days prior to the

originally stated or any extended expiration date. In the event the BLM is notified of the financial institution's intent not to renew the letter of credit, the principal must extend the letter of credit or provide an adequate replacement bond with an assumption of liability rider. If the BLM does not receive an adequate notice or replacement bond with rider, the BLM will collect the letter of credit within 30 days of the expiration without further notification to the obligor.

§ 3104.20 Lease bond.

The operator, a lessee, or an owner of operating rights (sublessee) must be covered by a bond in its own name as principal or obligor in an amount of not less than the amount specified in 43 CFR 3104.1 for each lease conditioned upon compliance with all of the terms of the lease. Where two or more lease interest holders have interests in different formations or portions of the lease, separate bonds may be posted. The operator shall be covered by a bond in his/her own name as principal, or a bond in the name of the lessee or sublessee, provided that a consent of the surety, or the obligor in the case of a personal bond, to include the operator under the coverage of the bond is furnished to the BLM office maintaining the bond.

§ 3104.30 Statewide bonds.

In lieu of lease bonds, lessees, owners of operating rights (sublessees), or operators may furnish a bond in an amount of not less than the amount specified in 43 CFR 3104.1 covering all leases and operations in any one State.

§ 3104.40 Surface owner protection bond.

(a) If a good-faith effort by the Federal lessee, its operator, or representatives has not resulted in an agreement with the surface owner under 43 CFR 3171.19, the authorized officer will require an adequate surface owner protection bond in an amount sufficient to indemnify the surface owner against the reasonable and foreseeable damages to crops and tangible improvements from the proposed operations that would not otherwise be covered by a bond held by the BLM. This surface owner protection bond is not part of the bond obligations under lease or statewide bonds.

(b) The surface owner protection bond must be provided on a BLM-approved form.

(c) The surface owner protection bond may be a personal or surety bond and must be not less than $1,000.

(d) The BLM will notify the surface owner of the proposed surface owner protection bond amount.

(e) If the surface owner objects to the sufficiency of the surface owner protection bond, the BLM authorized officer will determine the sufficiency of the bond necessary to indemnify the surface owner for the reasonable and foreseeable damages to crops and tangible improvements.

§ 3104.50 Increased amount of bonds.

(a) When an operator desiring approval of an APD has caused the BLM, or a surface management agency, to make a demand for payment under a bond or other financial guarantee within the 5-year period prior to submission of the APD, due to failure to plug a well or reclaim lands completely in a timely manner, the authorized officer will require, prior to approval of the APD, a bond in an amount equal to the costs, when higher than the minimum bond amounts, as estimated by the authorized officer of plugging the well and reclaiming the disturbed area involved in the proposed operation, or in the minimum amount as prescribed in this subpart, whichever is greater.

(b) The authorized officer may require an increase in the amount of any bond whenever it is determined that the operator poses a risk due to factors, including, but not limited to, a history of previous violations, a notice from the ONRR that there are uncollected royalties due, or the total cost of plugging existing wells and reclaiming lands exceeds the present bond amount based on the estimates determined by the authorized officer. The increase in bond amount may be to any level specified by the authorized officer, but in no circumstances will it exceed the total of the estimated costs of plugging and reclamation, the amount of uncollected royalties due to the ONRR, plus the amount of money owed to the lessor due to previous violations remaining outstanding.

§ 3104.60 Where filed and number of copies.

All bonds must be filed in the proper BLM office on a current form approved by the Director. A single copy executed by the principal or, in the case of surety bonds, by both the principal and an acceptable surety is sufficient. A bond filed on a form not currently in use will be acceptable, unless such form has been declared obsolete by the Director prior to the filing of such bond. For purposes of 43 CFR 3104.20 and 3104.30, bonds or bond riders must be filed in the BLM State office having jurisdiction over the lease or operations covered by the bond or rider.

§ 3104.70 Default.

(a) Where, upon a default, the surety makes a payment to the United States of an obligation incurred under a lease, the face amount of the surety bond or personal bonds and the surety's liability thereunder will be reduced by the amount of such payment.

(b) After default, where the obligation in default equals or is less than the face amount of the bond(s), the principal must either post a new bond or restore the existing bond(s) to the amount previously held or a larger amount as determined by the authorized officer. In lieu thereof, the principal may file separate bonds for each lease covered by the deficient bond(s). Where the obligation incurred exceeds the face amount of the bond(s), the principal must make full payment to the United States for all obligations incurred that are in excess of the face amount of the bond(s) and must post a new bond in the amount previously held or such larger amount as determined by the authorized officer. The restoration of a bond or posting of a new bond must be made within 6 months or less after receipt of notice from the authorized officer. Failure to comply with these requirements may:

(1) Subject all leases covered by such bond(s) to cancellation under the provisions of 43 CFR 3108.30; and

(2) Result in the bond obligor or principal being referred to the Department's Suspension and Debarment Program under 2 CFR part 1400 to determine if the person will be suspended or debarred from doing business with the Federal Government.

§ 3104.80 Termination of period of liability.

The authorized officer will not give consent to termination of the period of liability of any bond unless an acceptable replacement bond has been filed or until all the terms and conditions of the lease have been met.

§ 3104.90 Unit Operator and nationwide bonds held prior to June 22, 2024.

Unit operator and nationwide bonds accepted by the BLM prior to June 22, 2024, must be replaced with individual lease or statewide bonds by June 22, 2025. The BLM will not accept any new unit operator or nationwide bonds.

Subpart 3105—Cooperative Conservation Provisions

§ 3105.10 Cooperative or unit agreement.

(a) The suggested contents of such an agreement and the procedures for

obtaining approval are contained in 43 CFR part 3180.

(b) An application to form a unit agreement, a unit expansion, or a designation of a successor operator must include the processing fee found in the fee schedule in § 3000.120 of this chapter.

Communitization Agreements

§ 3105.21 Where filed.

(a) An application to form a communitization agreement or modify an existing agreement must be filed with the proper BLM office for final approval.

(b) An application for a communitization agreement must include:

(1) A statement as to whether the proposed communitization agreement deviates from the BLM's current model communitization agreement form, and a certification that the applicant received the required signatures;

(2) An Exhibit A displaying a map of the area covered by the proposed agreement and the separate agreement tracts; and

(3) An Exhibit B displaying the separate tracts and ownership;

(c) To ensure accurate reporting to ONRR, an application for a communitization agreement should be submitted at least 90 calendar days prior to first production.

(d) An application for designations of successor operator for a communitization agreement must include the processing fee found in the fee schedule in § 3000.120 of this chapter.

§ 3105.22 Purpose.

When a lease or a portion thereof cannot be independently developed and operated in conformity with an established well-spacing or well-development program, the authorized officer may approve a communitization agreement for such lands with other lands, whether or not owned by the United States, upon a determination that it is in the public interest. Operations or production under such an agreement will be deemed to be operations or production as to each lease committed thereto.

§ 3105.23 Requirements.

(a) The communitization agreement must describe the separate tracts comprising the drilling or spacing unit, must show the apportionment of the production or royalties to the several parties, the name of the operator, and contain adequate provisions for the protection of the interests of the United States. The agreement must be signed by or on behalf of all necessary parties and must be filed prior to the expiration of the Federal lease(s) involved in order to confer the benefits of the agreement upon such lease(s).

(b) The agreement will be effective as to the Federal lease(s) involved only if approved by the authorized officer. Approved communitization agreement are considered effective from the date of the agreement or from the date of the onset of production from the communitized formation, whichever is earlier, except when the spacing unit is subject to a State pooling order after the date of first sale, then the effective date of the agreement will be the effective date of the order.

(c) The public interest requirement for an approved communitization agreement will be satisfied only if the well dedicated thereto has been completed for production in the communitized formation at the time the agreement is approved or, if not, that the operator thereafter commences and/or diligently continues drilling operations to a depth sufficient to test the communitized formation or establishes to the satisfaction of the authorized officer that further drilling of the well would be unwarranted or impracticable. If an application is received for voluntary termination of a communitization agreement during its fixed term or such an agreement automatically expires at the end of its fixed term without the public interest requirement having been satisfied, the approval of that agreement by the authorized officer will be invalid and no Federal lease included in the communitization agreement will be eligible for an extension under 43 CFR 3107.40.

§ 3105.24 Communitization agreement terms.

The communitization agreement will remain in effect for a period of 2 years from the effective date or approval date, whichever is later, and so long thereafter as communitized substances may be produced in paying quantities, or as otherwise specified in the agreement.

Operating, Drilling, or Development Contracts

§ 3105.31 Where filed.

A contract submitted for approval under this section must be filed with the proper BLM office.

§ 3105.32 Purpose.

Approval of operating, drilling or development contracts will be granted only to permit operators or pipeline companies to enter into contracts with a number of lessees sufficient to justify operations on a scale large enough to justify the discovery, development, production or transportation of oil or gas and to finance the same.

§ 3105.33 Requirements.

The contract must be accompanied by a statement showing all the interests held by the contractor in the area or field and the proposed or agreed plan for development and operation of the field. All the contracts held by the same contractor in the area or field must be submitted for approval at the same time and full disclosure of the projects made.

Subsurface Storage of Oil and Gas

§ 3105.41 Where filed.

(a) Applications for subsurface storage or designations of successor operator must be filed in the proper BLM office.

(b) The final gas storage agreement signed by all the parties in interest must be submitted to the BLM.

(c) Applications for subsurface storage agreements or designations of successor operator must include the processing fee found in the fee schedule in § 3000.120 of this chapter.

§ 3105.42 Purpose.

To avoid waste and to promote conservation of natural resources, the Secretary, upon application by the interested parties, may authorize the subsurface storage of oil and gas, whether or not produced from lands owned by the United States. Such authorization will provide for the payment of such storage fee or rental on the stored oil or gas as may be determined adequate in each case, or, in lieu thereof, for a royalty other than that prescribed in the lease when such stored oil or gas is produced in conjunction with oil or gas not previously produced. The BLM will require a bond as provided under § 3104 for operations conducted in a subsurface storage agreement.

§ 3105.43 Requirements.

The agreement must disclose the ownership of the lands involved, the parties in interest, the storage fee, rental or royalty offered to be paid for such storage and all information demonstrating such storage would avoid waste and promote the conservation of natural resources.

§ 3105.44 Extension of lease term.

Any lease used for the storage of oil or gas will be extended for the period of storage under an approved agreement. The obligation to pay annual lease rent continues during the extended period.

§ 3105.50 Consolidation of leases.

(a) Leases may be consolidated upon written request of the lessee filed with the proper BLM office. The request must identify each lease involved by serial number and justify the consolidation. Each request for a consolidation of leases must include the processing fee found in the fee schedule in § 3000.120 of this chapter.

(b) All parties holding any undivided interest in any lease involved in the consolidation must agree to enter into the same lease consolidation.

(c) Leases containing different types of lands (public domain lands vs. acquired lands), mixed fractional mineral interest, or provisions required by law that cannot be reconciled, will not be consolidated.

(d) Consolidation of leases will not exceed acreage limits of 2,560 acres for competitive leases and 10,240 acres for noncompetitive leases.

(e) The effective date, the anniversary date, and the primary term of the consolidated lease will be those of the oldest original lease included in the consolidation. The term of a consolidated lease may be extended beyond the primary lease term under subpart 3107.

(f) The highest royalty and rental rates of the each of the leases to be consolidated will apply to the consolidated lease.

(g) Lease stipulations and other terms and conditions of each original lease, except as noted in paragraphs (e) and (f) of this section, will continue to apply to that lease or any portion thereof regardless of the lease becoming a part of a consolidated lease.

Subpart 3106—Transfers by Assignment, Sublease, or Otherwise

§ 3106.10 Transfers, general.

(a) Leases may be transferred by assignment or sublease as to all or part of the acreage in the lease or as to either a divided or undivided interest therein.

(b) An assignment of the record title conveys both record title and operating rights, unless operating rights have been severed from the record title through an approved transfer of operating rights. Thereafter, the operating rights and record title may each be subject to further transfers.

(c) An assignment of a separate zone, deposit, depth, formation, specific well, or of part of a legal subdivision, will be denied.

(d) Within the boundaries of a Federal lease, operating rights may only be divided with respect to legal subdivisions, depth ranges, and formations.

(e) An assignment of less than 640 acres outside Alaska or of less than 2,560 acres within Alaska will be denied unless the assignment constitutes the entire lease or is demonstrated to further the development of oil and gas to the satisfaction of the authorized officer. Reference 43 CFR 3102.51(g) for certification of compliance.

(f) The rights of the transferee to a lease or an interest therein will not be recognized by the Department until the transfer has been approved by the authorized officer.

(g) A transfer may be withdrawn in writing, signed by the transferor and the transferee, if the transfer has not been approved by the authorized officer.

(h) A request for approval of a transfer of a lease or interest in a lease must be filed within 90 days from the date of its execution. The 90-day filing period will begin on the date the transferor signs and dates the transfer. If the transfer is filed after the 90th day, the authorized officer may require verification that the transfer is still in force and effect.

(i) A transfer of production payments or overriding royalty or other similar payments, arrangements, or interests must be filed in the proper BLM office but will not require approval.

(j) No transfer of an offer to lease or interest in a lease will be approved prior to the issuance of the lease.

§ 3106.20 Qualifications of assignees and transferees.

Assignees and transferees must comply with the provisions of 43 CFR subpart 3102 and post any bond that may be required. Only responsible and qualified lessees may own, hold, or control an interest in a lease.

§ 3106.30 Fees.

(a) Each transfer of record title or of operating rights (sublease) for each lease must include payment of the processing fee for assignments and transfers found in the fee schedule in § 3000.120 of this chapter.

(b) Each transfer of overriding royalty or payment out of production must include payment of the processing fee for overriding royalty transfers or payments out of productions found in the fee schedule in § 3000.120 of this chapter for each lease to which it applies.

Forms

§ 3106.41 Transfers of record title and of operating rights (subleases).

Each transfer of record title or of an operating right (sublease) must be filed with the proper BLM office on a current form approved by the Director. A separate form for each transfer, in triplicate, must be filed for each lease out of which a transfer is made. The BLM does not require triplicate copies of the assignment or transfer when it is electronically submitted. Copies of documents other than the current form approved by the Director must not be submitted. However, reference(s) to other documents containing information affecting the terms of the transfer may be made on the submitted form.

§ 3106.42 Transfers of other interests, including royalty interests and production payments.

(a) Each transfer of overriding royalty interest, payment out of production or similar interests created or reserved must be described for each lease on the current assignment or transfer form when filed.

(b) A single executed copy of each such transfer of other interests for each lease must be filed with the proper BLM office.

§ 3106.43 Mass transfers.

(a) A mass transfer may be utilized in lieu of the provisions of 43 CFR 3106.41 and 3106.42 when an assignor or transferor transfers interests of any type in more than one Federal lease to the same assignee or transferee.

(b) The mass transfer must be filed with each proper BLM office administering any lease affected by the mass transfer. The transfer must be on a current form approved by the Director with an exhibit attached to each copy listing the following for each lease:

(1) The serial number;

(2) The type and percent of interest being conveyed; and

(3) A description of the lands affected by the transfer in accordance with 43 CFR 3106.50.

(c)(1) One duplicate copy of the form must be filed with the proper BLM office for each lease involved in the mass transfer. A copy of the exhibit for each lease may be limited to line items pertaining to individual leases as long as that line item includes the information required by paragraph (b) of this section. The BLM does not require a duplicate copy of the assignment or transfer when it is electronically submitted.

(2) When the BLM does not receive the requisite number of copies, the applicant must reimburse the BLM for the full costs incurred to make the required number of copies. The BLM will waive fees under one dollar.

(d) A mass transfer must include the processing fee for assignments and transfers found in the fee schedule in § 3000.120 of this chapter for each such interest transferred for each lease.

§ 3106.50 Description of lands.

Each assignment of record title must describe the lands involved in the same manner as the lands are described in the lease, except no land description is required when 100 percent of the entire area encompassed within a lease is conveyed.

§ 3106.60 Bond requirements.

Where the lessee or operating rights owner (sublessee) maintains a bond covering the lease, the assignee of record title interest or transferee of operating rights in such lease must furnish, if bond coverage continues to be required, a proper bond that will cover any obligations arising under the lease to the same extent as the assignor's or transferor's bond.

Approval of Transfer or Assignment

§ 3106.71 Failure to qualify.

The BLM will not approve any assignment of record title or transfer of operating rights (sublease) if any party in interest is not a qualified lessee, or if the bond is insufficient. The BLM approves assignments and transfers for administrative purposes only. Approval does not warrant or certify that either party to a transfer holds legal or equitable title to a lease.

§ 3106.72 Continuing obligation of an assignor or transferor.

(a) The lessee or sublessee remains responsible for performing all obligations under the lease until the date the BLM approves an assignment of record title interest or transfer of operating rights.

(b) After the BLM approves the assignment or transfer, the assignor or transferor will continue to be responsible for lease obligations that accrued before the approval date, whether or not such obligations were identified at the time of the assignment or transfer. This includes paying compensatory royalties for drainage. It also includes responsibility for plugging wells drilled and removing facilities installed or used before the effective date of the assignment or transfer.

§ 3106.73 Lease account status.

The BLM will not approve a transfer if the lease account is delinquent with respect to: royalty payments; lease obligations, such as, but not limited to, rent and minimum royalty; or production reporting to ONRR for a lease in non-terminable status.

§ 3106.74 Effective date of transfer.

The signature of the authorized officer on the official form will constitute approval of the assignment of record title or transfer of operating rights (sublease) which will take effect as of the first day of the lease month following the date of filing in the proper BLM office of all documents and statements required by this subpart and an appropriate bond, if one is required.

§ 3106.75 Effect of transfer.

An assignment of record title to 100 percent of a portion of the lease segregates the transferred portion and the retained portion into separate leases. Each resulting lease retains the anniversary date and the terms and conditions of the original lease. An assignment of record title to less than 100 percent of a portion of the lease or a transfer of operating rights (sublease) will not segregate the transferred and retained portions into separate leases.

§ 3106.76 Obligations of assignee or transferee.

(a) The assignee of record title agrees to comply with the terms of the original lease during the lease tenure. The assignee assumes the responsibility to plug and abandon all wells which are no longer capable of producing, reclaim the lease site, and remedy all environmental problems in existence and that a purchaser exercising reasonable diligence should have known existed at the time of the transfer. When required, the record title holder must also maintain an adequate bond to ensure performance of these responsibilities.

(b) The transferee of operating rights agrees to comply with the terms of the original lease as it applies to the area or horizons for the interest acquired. The transferee assumes the responsibility to plug and abandon all wells that are no longer capable of producing, reclaim the lease site, and remedy all environmental problems in existence and that a purchaser exercising reasonable diligence should have known existed at the time of the transfer. When required, the operating rights holder must also maintain an adequate bond to ensure performance of these responsibilities.

Other Types of Transfers

§ 3106.81 Heirs and devisees.

(a) If an offeror, applicant, lessee or transferee dies, their rights would be assigned or transferred to the heirs, devisees, executor or administrator of the estate, as appropriate, upon the filing of legal documents demonstrating that the assignee or transferee is recognized as the successor of the deceased.

(b) The filing must include the processing fee for the transfer to an heir/devisee found in the fee schedule in § 3000.120 of this chapter with the request to assign lease rights.

(c) The filing must include a qualification statement demonstrating qualification to hold an interest in a lease in accordance with 43 CFR subpart 3102. Any ownership or interest otherwise forbidden by the regulations in this part which may be acquired by descent, will, judgment or decree may be held for a period not to exceed 2 years after its acquisition. Any such forbidden ownership or interest held for a period of more than 2 years after acquisition may be subject to cancellation.

(d) A bond rider or replacement bond may be required for any bond(s) previously furnished by the decedent.

§ 3106.82 Change of name.

(a) A legally recognized change of name of a lessee or sublessee must be reported to the proper BLM office. The notice of name change must be submitted in writing with adequate information concerning the name change. For a corporate name change, the request must include the Secretary of State's Certificate of Name Change, along with the Articles of Incorporation, or Amendment, if available.

(b) An entity must include with the notice of name change the required processing fee listed in the fee schedule in § 3000.120 of this chapter.

(c) If a bond(s) has been furnished, a change of name on the bond may be made by surety consent or a rider to the original bond or by a replacement bond.

§ 3106.83 Corporate mergers and dissolution of corporations, partnerships, and trusts.

(a) In the event a corporate merger affects leases where property of the dissolving corporation to the surviving corporation is accomplished by operation of law, an assignment of any affected lease interest is not required. An entity must notify the BLM of the merger and provide copies of the Secretary of State's Certificate of Merger, along with the Articles of Incorporation, or Amendment, if available, to the BLM.

(b) The BLM will not recognize any transfers provided by the Articles of Dissolution unless an entity has filed with the BLM a Certificate of Dissolution of an incorporated entity, certified as accepted by the State where the entity was incorporated.

(c) An entity must file with the BLM a dissolution of a partnership or trust through an order or decree that authorizes settlement, discharge, and distribution of the lease holdings and/or interests for official recognition of the assignment of lease interests.

(d) An entity must include the processing fee for corporate merger or dissolution of corporation, partnership, or trust found in the fee schedule in § 3000.120 of this chapter.

(e) The authorized officer may require a bond rider or replacement bond for all affected corporations, partnerships or trusts.

§ 3106.84 Sheriff's sale/deed.

(a) Where a notice of sale of the leasehold interest is published pursuant to State law applicable to the execution of sales of real property, the purchaser must submit a copy of the Sheriff's Certificate of Sale to the proper BLM office after any redemption period has passed.

(b) When submitting the certificate described in paragraph (a), an entity must include the processing fee for sheriff's deed found in the fee schedule in § 3000.120 of this chapter.

(c) The purchaser(s) must file a qualification statement to hold an interest in a lease in accordance with 43 CFR subpart 3102. Failure to provide a qualification statement after 2 years will result in the BLM cancelling the lease or interest.

(d) If a bond has been furnished by the previous interest holder, the authorized officer may require a new bond.

Subpart 3107—Continuation and Extension

§ 3107.10 Extension by drilling.

(a) Any lease on which actual drilling operations were commenced prior to the end of its primary term and are being diligently prosecuted at the end of the primary term or any lease which is part of an approved oil and gas agreement upon which such drilling takes place, will be extended for 2 years subject to the rental being timely paid as required by 43 CFR 3103.20, and subject to the provisions of 43 CFR 3105.23 and appendix A to part 3180, if applicable. The BLM will not grant a drilling extension for a lease in its extended term.

(b) Actual drilling operations must be conducted in a manner that a reasonable person seriously looking for oil or gas could be expected to make in that particular area, given the existing knowledge of geologic and other pertinent facts. In drilling a new well on a lease or for the benefit of a lease under the terms of an approved agreement, it must be taken to a depth sufficient to penetrate at least one formation recognized in the area as potentially productive of oil or gas, or where an existing well is reentered, it must be taken to a depth sufficient to penetrate at least one new and deeper formation recognized in the area as potentially productive of oil or gas. The authorized officer may determine that further drilling is unwarranted or impracticable.

(c) When a BLM-approved directional or horizontal well is drilled within the leased area from an off-lease location with the intent to produce from the leased area, the BLM will consider drilling to have commenced on the leased area when drilling is commenced at the off-lease location.

Production

§ 3107.21 Continuation by production.

A lease will be extended so long as oil or gas is being produced in paying quantities.

§ 3107.22 Cessation of production.

A lease in its extended term because of production (and lacking a well capable of production in paying quantities) will not expire upon cessation of production, if, within 60 calendar days of cessation of production, reworking or drilling operations on the leasehold are commenced and are thereafter conducted with reasonable diligence during the period of nonproduction. If these reworking or drilling operations fail to result in production in paying quantities, the lease will expire by operation of law, effective as of the date paying production ceased.

§ 3107.23 Leases capable of production.

No lease for lands on which there is a well capable of producing oil or gas in paying quantities will expire because the lessee fails to produce the same, unless the lessee fails to place the lease in production within a period of not less than 60 calendar days as specified by the authorized officer after receipt of notice by certified mail from the authorized officer to do so. Such production must be continued unless and until suspension of production is granted by the authorized officer.

Extension of Leases Within Agreements

§ 3107.31 Leases committed to an agreement.

(a) Any lease or portion of a lease committed to an oil and gas agreement that contains a general provision for allocation of oil or gas will continue in effect so long as the lease or portion thereof remains subject to the agreement; *provided,* that there is production of oil or gas in paying quantities under the agreement prior to the expiration date of such lease.

(b) A well that is drilled and completed on a lease committed to a unit agreement, and that is capable of production in paying quantities on a lease basis, will extend the term of all expiring Federal leases committed to the unit agreement for the term of the unit agreement and so long as the well is capable of production in paying quantities.

§ 3107.32 Segregation of leases committed in part.

(a) Any lease committed after July 29, 1954, to any unit agreement, which covers lands within and lands outside the area covered by the agreement, will be segregated, as of the effective date of commitment to the unit, into separate leases; one covering the lands committed to the agreement, the other lands not committed to the agreement. For unproven areas, such segregation will occur only when the public interest requirement is satisfied pursuant to 43 CFR 3183.4(b). Upon satisfaction of the public interest requirement, the BLM will deem the segregation to have been effective as of the date of commitment of the lands to the unit.

(b)(1) The segregated lease covering the non-unitized portion of the lands will continue in force and effect for the term of the lease or for 2 years from the date of segregation, whichever is longer.

(2) If a partially committed lease is in an extended term because of production, the segregated, non-producing lease will continue in effect so long as the producing lease exists and rentals are paid, and so long thereafter as oil or gas is produced from the committed lease.

§ 3107.40 Extension by elimination.

Any lease eliminated from any approved or prescribed oil and gas agreement authorized by the Act and any lease in effect at the termination of such agreement, unless relinquished, will continue in effect for the original term of the lease or for 2 years after its elimination from the agreement or after the termination of the plan or agreement, whichever is longer, and for so long thereafter as oil or gas is produced in paying quantities. No lease will be extended if the public interest requirement for an approved oil and gas agreement has not been satisfied, as determined by the authorized officer.

Extension of Leases Segregated by Assignment

§ 3107.51 Extension after discovery on other segregated portions.

Any lease segregated by assignment, including the retained portion, will continue in effect for the primary term

of the original lease, or for 2 years after the date a well capable of production in paying quantities is established upon any other portion of the original lease, whichever is the longer period.

§ 3107.52 Undeveloped parts of leases in their extended term.

Undeveloped parts of leases retained or assigned out of leases which are in their extended term will continue in effect for 2 years after the effective date of assignment, provided the parent lease was issued prior to September 2, 1960.

§ 3107.53 Undeveloped parts of producing leases.

Undeveloped parts of leases retained or assigned out of leases which are extended by production, actual or suspended, or the payment of compensatory royalty will continue in effect for 2 years after the effective date of assignment and for so long thereafter as oil or gas is produced in paying quantities.

§ 3107.60 Extension of reinstated leases.

Where a reinstatement of a terminated lease is granted under 43 CFR 3108.20 and the authorized officer finds that the reinstatement will not afford the lessee a reasonable opportunity to continue operations under the lease, the authorized officer may extend the term of such lease for a period sufficient to give the lessee such an opportunity. Any extension will be subject to the following conditions:

(a) No extension will exceed a period equal to the unexpired portion of the lease or any extension thereof remaining at the date of termination.

(b) When the reinstatement occurs after the expiration of the term or extension thereof, the lease may be extended from the date the authorized officer grants the petition, but in no event for more than 2 years from the date the reinstatement is authorized and so long thereafter as oil or gas is produced in paying quantities.

Other Extension Types

§ 3107.71 Payment of compensatory royalty.

The payment of a compensatory royalty will extend the term of any lease for the period during which such compensatory royalty is paid and for a period of 1 year from the discontinuance of such payments.

§ 3107.72 Subsurface storage of oil and gas.

Any lease used for the storage of oil or gas will be extended for the period of storage under an approved agreement.

Subpart 3108—Relinquishment, Termination, Cancellation

§ 3108.10 Relinquishment.

The lessee(s) may relinquish the lease or any legal subdivision of the lease at any time. The lessee(s) must file a written relinquishment with the BLM State Office with jurisdiction over the lease. All lessees holding record title interests in the lease must sign the relinquishment. A relinquishment takes effect on the date the lessee filed it with the BLM. However, the lessee(s) and the party that issued the bond will continue to be obligated to:

(a) Make payments of all accrued rentals and royalties, including payments of compensatory royalty due for all drainage that occurred before the relinquishment;

(b) Place all wells to be relinquished in condition for suspension or abandonment as the BLM requires; and

(c) Complete reclamation of the leased sites after stopping or abandoning oil and gas operations on the lease, under a plan approved by the BLM or the appropriate surface management agency.

Termination by Operation of Law and Reinstatement

§ 3108.21 Automatic termination.

(a) Except as provided in paragraph (b) of this section, any lease on which there is no well capable of producing oil or gas in paying quantities will automatically terminate by operation of law (30 U.S.C. 188) if the lessee fails to pay the rental at the designated ONRR office on or before the lease anniversary date. However, if the designated ONRR office is closed on the anniversary date, a rental payment received on the next business day the ONRR office is open to the public will be considered timely made.

(b) If the rental payment due under a lease is paid on or before its anniversary date but the amount of the payment is deficient and the deficiency is nominal as defined in this section, or the amount of payment made was determined in accordance with the rental or acreage figure stated in a decision rendered by the authorized officer, and such figure is found to be in error resulting in a deficiency, such lease will not have automatically terminated unless the lessee fails to pay the deficiency within the period prescribed in the Notice of Deficiency provided for in this section. A deficiency will be considered nominal if it is not more than $100 or more than 5 percent of the total payment due, whichever is less. The designated ONRR office will send a Notice of Deficiency to the lessee. The Notice will allow the lessee 15 days from the date of receipt or until the due date, whichever is later, to submit the full balance due to the designated ONRR office. If the payment required by the Notice is not paid within the time allowed, the lease will have terminated by operation of law as of its anniversary date.

(c) The automatic termination provision does not apply where, due to other contingencies, additional rental is due on a date other than the lease anniversary date and where the lessee did not receive notice that the obligation had accrued, unless the lessee fails to pay the rental within the period prescribed in the BLM Notice.

§ 3108.22 Reinstatement at existing rental and royalty rates: Class I reinstatements.

(a) Except as hereinafter provided, the authorized officer may reinstate a lease which has terminated for failure to pay on or before the anniversary date the full amount of rental due, provided that:

(1) Such rental was paid or tendered within 20 days after the anniversary date; and

(2) It is shown to the satisfaction of the authorized officer that the failure to timely submit the full amount of the rental due was either justified or not due to a lack of reasonable diligence on the part of the lessee (reasonable diligence includes a rental payment that is paid to the ONRR on or before the lease anniversary date. If the designated ONRR office or payment system is not operational on the anniversary date, payment received on the next business day in which the designated ONRR office or payment system is operational to the public will be deemed timely); and

(3) A petition for reinstatement and the processing fee for lease reinstatement, Class I, found in the fee schedule in § 3000.120 of this chapter, are filed with the proper BLM office within 60 days after receipt of Notice of Termination of Lease due to late payment of rental. If a terminated lease becomes productive prior to the time the lease is reinstated, all required royalty that has accrued must be paid to the ONRR.

(b) The burden of showing that the failure to pay on or before the anniversary date was justified or not due to lack of reasonable diligence is on the lessee.

(c) Under no circumstances will a terminated lease be reinstated if:

(1) A valid oil and gas lease has been issued prior to the filing of a petition for reinstatement affecting any of the lands covered by that terminated lease; or

(2) The oil and gas interests of the United States in the lands have been disposed of or otherwise have become unavailable for leasing.

§ 3108.23 Reinstatement at higher rental and royalty rates: Class II reinstatements.

(a) The authorized officer may, if the requirements of this section are met, reinstate a competitive oil and gas lease which was terminated by operation of law for failure to pay rental timely when the rental was not paid or tendered within 20 calendar days of the termination date, and it is shown to the satisfaction of the authorized officer that such failure was justified or not due to a lack of reasonable diligence, or no matter when the rental was paid, it is shown to the satisfaction of the authorized officer that such failure was inadvertent.

(b)(1) Such leases may be reinstated if the required back rental and royalty at the increased rates accruing from the date of termination, together with a petition for reinstatement, are filed on or before the earlier of:

(i) Sixty calendar days after the last date that any lessee of record received Notice of Termination by certified mail; or

(ii) Twenty-four months after termination of the lease.

(2) After determining that the requirements for filing of the petition for reinstatement have been timely met, the authorized officer may reinstate the lease if:

(i) No valid lease has been issued prior to the filing of the petition for reinstatement affecting any of the lands covered by the terminated lease, whether such lease is still in effect or not;

(ii) The oil and gas interests of the United States in the lands have not been disposed of or have not otherwise become unavailable for leasing;

(iii) Payment of all back rentals and royalties at the rates established for the reinstated lease has been made;

(iv) An agreement has been signed by the lessee and attached to and made a part of the lease specifying future rentals at the applicable rates specified for reinstated leases in 43 CFR 3103.22 and future royalties at the rates set in 43 CFR 3103.31 for all production removed or sold from such lease or shared by such lease from production allocated to the lease by virtue of its participation in an oil and gas agreement;

(v) A notice of the proposed reinstatement of the terminated lease and the terms and conditions of reinstatement has been published in the **Federal Register** at least 30 days prior to the date of reinstatement for which the lessee must reimburse the BLM for the full costs incurred in the publishing of said notice; and

(vi) The lessee has paid the BLM a nonrefundable administrative fee of $500.

(c) The authorized officer will furnish to the Chairpersons of the Committee on Natural Resources of the House of Representatives and of the Committee on Energy and Natural Resources of the Senate, at least 30 days prior to the date of reinstatement, a copy of the notice, together with information concerning rental, royalty, volume of production, if any, and any other matter which the authorized officer considers significant in making the determination to reinstate.

(d) If the authorized officer reinstates the lease, the reinstatement will be effective as of the date of termination, for the unexpired portion of the original lease or any extension thereof remaining on the date of termination, and so long thereafter as oil or gas is produced in paying quantities. Where a lease is reinstated under this section and the authorized officer finds that the reinstatement of such lease either:

(1) Occurs after the expiration of the primary term or any extension thereof; or

(2) Will not afford the lessee a reasonable opportunity to continue operations under the lease, the authorized officer may extend the term of the reinstated lease for such period as determined reasonable, but in no event for more than 2 years from the date of the reinstatement and so long thereafter as oil or gas is produced in paying quantities.

§ 3108.30 Cancellation.

(a) Whenever the lessee fails to comply with any of the provisions of the law, the regulations issued thereunder, or the lease, the lease may be canceled by the Secretary, if the leasehold does not contain a well capable of production of oil or gas in paying quantities, or if the lease is not committed to an approved oil and gas agreement that contains a well capable of production of unitized substances in paying quantities. The lease may be canceled only if the default continues for 30 calendar days after a notice of default has been delivered in accordance with 43 CFR 1810.2.

(b) Whenever the lessee fails to comply with any of the provisions of the law, the regulations issued thereunder, or the lease, and if the leasehold contains a well capable of production of oil or gas in paying quantities, or if the lease is committed to an approved oil and gas agreement that contains a well capable of production of unitized substances in paying quantities, the lease may be canceled only by court order in the manner provided by section 31(a) of the Act (30 U.S.C. 188).

(c) If any interest in any lease is owned or controlled, directly or indirectly, by means of stock or otherwise, in violation of any of the provisions of the Act, the lease may be canceled, or the interest so owned may be forfeited, or the person so owning or controlling the interest may be compelled to dispose of the interest, only by court order in the manner provided by section 27(h)(1) of the Act (30 U.S.C. 184).

(d) Leases will be subject to cancellation if improperly issued.

§ 3108.40 Bona fide purchasers.

A lease or interest therein may not be cancelled to the extent that such action adversely affects the title or interest of a *bona fide* purchaser even though such lease or interest, when held by a predecessor in title, may have been subject to cancellation. All purchasers will be charged with constructive notice as to all pertinent regulations and all BLM records pertaining to the lease and the lands covered by the lease. Prompt action may be taken to dismiss as a party to any proceedings with respect to a violation by a predecessor of any provisions of the Act, any person who shows the holding of an interest as a *bona fide* purchaser without having violated any provisions of the Act. No hearing will be necessary upon such showing unless prima facie evidence is presented that the purchaser is not a *bona fide* purchaser.

§ 3108.50 Waiver or suspension of lease rights.

If, during any proceeding with respect to a violation of any provision of the regulations in 43 CFR parts 3000 and 3100 or the Act, a party thereto files a waiver of his/her rights under the lease to drill or to assign his/her lease interests, or if such rights are suspended by order of the Secretary pending a decision, payments of rentals and the running of time against the term of the lease involved will be suspended as of the first day of the month following the filing of the waiver or the Secretary's suspension until the first day of the month following the final decision in the proceeding or the revocation of the waiver or suspension.

Subpart 3109—Leasing under Special Acts

Rights-of-Way

§ 3109.11 Generally.

The Act of May 21, 1930 (30 U.S.C. 301–306), authorizes either the leasing of oil and gas deposits under railroad and other rights-of-way to the owner of the right-of-way or the entering of a compensatory royalty agreement with adjoining landowners. This authority will be exercised only with respect to railroad rights-of-way and easements issued pursuant either to the Act of March 3, 1875 (43 U.S.C.934 *et seq.*), or pursuant to earlier railroad right-of-way statutes, and with respect to rights-of-way and easements issued pursuant to the Act of March 3, 1891 (43 U.S.C. 946 *et seq.*). The oil and gas underlying any other right-of-way or easement is included within any oil and gas lease issued pursuant to the Act which covers the lands within the right-of-way, subject to the limitations on use of the surface, if any, set out in the statute under which, or permit by which, the right-of-way or easement was issued, and such oil and gas will not be leased under the Act of May 21, 1930.

§ 3109.12 Application.

(a) No approved form is required for an application to lease oil and gas deposits underlying a right-of-way.

(b) The right-of-way owner or his/her transferee must file the application in the proper BLM office.

(c) Include the processing fee for leasing under right-of-way found in the fee schedule in § 3000.120 of this chapter.

(d) An application must include:

(1) Facts as to the ownership of the right-of-way, and of the transfer if the application is filed by a transferee;

(2) An executed transfer of the right to obtain a lease, if necessary;

(3) A description of the development of oil or gas in adjacent or nearby lands, the location and depth of the wells, the production and the probability of drainage of the deposits in the right-of-way;

(4) A description of each legal subdivision through which a portion of the right-of-way desired to be leased traverses; however, a description by metes and bounds of the right-of-way is not required; and

(5) A map of the applicable lands.

§ 3109.13 Notice.

After the BLM has determined that a lease of a right-of-way or any portion thereof is consistent with the public interest, either upon consideration of an application for lease or on its own motion, the authorized officer will serve notice on the owner or lessee of the oil and gas rights of the adjoining lands. The adjoining landowner or lessee will be allowed a reasonable time, as provided in the notice, within which to submit a bid for the percent of compensatory royalty, the owner or lessee must pay for the extraction of the oil and gas underlying the right-of-way through wells on such adjoining lands. The owner of the right-of-way will be given the same time period to submit a bid for the lease.

§ 3109.14 Award of lease or compensatory royalty agreement.

Award of lease to the owner of the right-of-way, or a contract for the payment of compensatory royalty by the owner or lessee of the adjoining lands will be made to the bidder whose offer is determined by the authorized officer to be to the best advantage of the United States, considering the amount of royalty to be received and the better development under the respective means of production and operation.

§ 3109.15 Compensatory royalty agreement or lease.

(a) The lease or compensatory royalty agreement will be on a form approved by the Director.

(b) The primary term of the lease will be for a period of 10 years.

(c) The following provisions of 43 CFR part 3100 apply to the issuance and administration of leases for oil and gas deposits underlying a right-of-way issued under this part:

(1) All of subpart 3101, except §§ 3101.21, 3101.22, 3101.23, 3101.24, and 3101.25; and

(2) All of subparts 3102 through 3108;

§ 3109.20 Units of the National Park System.

(a) Oil and gas leasing in units of the National Park System will be governed by 43 CFR part 3100 and all operations conducted on a lease or permit in such units will be governed by 43 CFR parts 3160 and 3180.

(b) Any lease or permit respecting minerals in units of the National Park System may be issued or renewed only with the consent of the Regional Director, National Park Service. Such consent will only be granted upon a determination by the Regional Director that the activity permitted under the lease or permit will not have significant adverse effect upon the resources or administration of the unit pursuant to the authorizing legislation of the unit. Any lease or permit issued will be subject to such conditions as may be prescribed by the Regional Director to protect the surface and significant resources of the unit, to preserve their use for public recreation, and to the condition that site specific approval of any activity on the lease will only be given upon concurrence by the Regional Director. All lease applications received for reclamation withdrawn lands will also be submitted to the Bureau of Reclamation for review.

(c) The units subject to the regulations in this part are those units of land and water which are shown on the following maps on file and available for public inspection in the office of the Director of the National Park Service and in the Superintendent's Office of each unit. The boundaries of these units may be revised by the Secretary as authorized in the Acts.

(1) Lake Mead National Recreation Area—The map identified as ''boundary map, 8360–80013B, revised February 1986.

(2) Whiskeytown Unit of the Whiskeytown-Shasta-Trinity National Recreation Area—The map identified as ''Proposed Whiskeytown-Shasta-Trinity National Recreation Area,'' numbered BOR–WST 1004, dated July 1963.

(3) Ross Lake and Lake Chelan National Recreation Areas—The map identified as ''Proposed Management Units, North Cascades, Washington,'' numbered NP–CAS–7002, dated October 1967.

(4) Glen Canyon National Recreation Area—the map identified as ''boundary map, Glen Canyon National Recreation Area,'' numbered GLC–91,006, dated August 1972.

(d) The following excepted units will not be open to mineral leasing:

(1) *Lake Mead National Recreation Area.* (i) All waters of Lakes Mead and Mohave and all lands within 300 feet of those lakes measured horizontally from the shoreline at maximum surface elevation;

(ii) All lands within the unit of supervision of the Bureau of Reclamation around Hoover and Davis Dams and all lands outside of resource utilization zones as designated by the Superintendent on the map (602–2291B, dated October 1987) of Lake Mead National Recreation Area which is available for inspection in the Office of the Superintendent.

(2) *Whiskeytown Unit of the Whiskeytown-Shasta-Trinity National Recreation Area.* (i) All waters of Whiskeytown Lake and all lands within 1 mile of that lake measured from the shoreline at maximum surface elevation;

(ii) All lands classified as high-density recreation, general outdoor recreation, outstanding natural and historic, as shown on the map numbered 611–20,004B, dated April

1979, entitled ''Land Classification, Whiskeytown Unit, Whiskeytown-Shasta-Trinity National Recreation Area.'' This map is available for public inspection in the Office of the Superintendent;

(iii) All lands within section 34 of Township 33 north, Range 7 west, Mt. Diablo Meridian.

(3) *Ross Lake and Lake Chelan National Recreation Areas.* (i) All of Lake Chelan National Recreation Area;

(ii) All lands within ½ mile of Gorge, Diablo and Ross Lakes measured from the shoreline at maximum surface elevation;

(iii) All lands proposed for or designated as wilderness;

(iv) All lands within ½ mile of State Highway 20;

(v) Pyramid Lake Research Natural Area and all lands within ½ mile of its boundaries.

(4) *Glen Canyon National Recreation Area.* Those units closed to mineral disposition within the natural zone, development zone, cultural zone and portions of the recreation and resource utilization zone as shown on the map numbered 80,022A, dated March 1980, entitled ''Mineral Management Plan—Glen Canyon National Recreation Area.'' This map is available for public inspection in the Office of the Superintendent and the office of the BLM State Offices, Arizona and Utah.

§ 3109.30 Shasta and Trinity Units of the Whiskeytown-Shasta-Trinity National Recreation Area.

Section 6 of the Act of November 8, 1965 (Pub. L. 89–336), authorizes the Secretary to permit the removal of oil and gas from lands within the Shasta and Trinity Units of the Whiskeytown-Shasta-Trinity National Recreation Area in accordance with the Act or the Mineral Leasing Act for Acquired Lands. Subject to the determination by the Secretary of Agriculture that removal will not have significant adverse effects on the purposes of the Central Valley project or the administration of the recreation area.

PART 3110 [REMOVED]

■ 3. Under the authority of 30 U.S.C. 189, part 3110 is removed.

■ 4. Revise part 3120 to read as follows:

PART 3120—COMPETITIVE LEASES

Sec.

PART 3120—COMPETITIVE LEASES

Authority: 16 U.S.C. 3101 *et seq.;* 30 U.S.C. 181 *et seq.* and 351–359; 40 U.S.C. 471 *et seq.;* 43 U.S.C. 1701 *et seq.;* Pub. L. 113–291, 128 Stat. 3762; and the Attorney General's Opinion of April 2, 1941 (40 Op. Atty. Gen. 41).

General

§ 3120.11 Lands available for competitive leasing.

All lands eligible and available for leasing may be offered for competitive auction under this subpart, including but not limited to:

(a) Lands that were covered by previously issued oil and gas leases that have terminated, expired, been cancelled or relinquished;

(b) Lands for which authority to lease has been delegated from the General Services Administration;

(c) If, in proceeding to cancel a lease, interest in a lease, option to acquire a lease or an interest therein, acquired in violation of any of the provisions of the Act, an underlying lease, interest or option in the lease is cancelled or forfeited through a bankruptcy or otherwise to the United States and there are valid interests therein that are not subject to cancellation, forfeiture, or compulsory disposition, such underlying lease, interest, or option may be sold to the highest responsible and qualified bidder by competitive bidding under this subpart, subject to all outstanding valid interests therein and valid options pertaining thereto. If less than the whole interest in the lease, interest, or option is cancelled or forfeited, such partial interest may likewise be sold by competitive bidding. If no satisfactory bid is obtained as a result of the competitive offering of such whole or partial interests, such interests may be sold in accordance with 30 U.S.C. 184(h)(2) by such other methods as the authorized officer deems appropriate, but on terms no less favorable to the United States than those of the best competitive bid received. Interest in outstanding leases(s) so sold will be subject to the terms and conditions of the existing lease(s);

(d) Lands which are otherwise unavailable for leasing but which are subject to drainage (protective leasing);

(e) Lands included in any expression of interest submitted to the authorized officer;

(f) Lands selected by the authorized officer; and

(g) Lands that were offered on a previous sale for which no bid was accepted or received.

§ 3120.12 Requirements.

(a) Each BLM state office will hold sales at least quarterly if eligible lands are available for competitive leasing.

(b) Lease sales will be conducted by a competitive auction process.

(c) The BLM may issue a lease only to the highest responsible and qualified bidder. If a person does not pay the minimum monies owed the day of the sale, the BLM may refer that person to the Department of the Interior's Office of the Inspector General, Administrative Remedies Division, for appropriate action, including potential suspension and debarment.

(d) The national minimum acceptable bid will be as specified in § 3103.1 of this chapter and payable on the gross acreage and will not be prorated for any lands in which the United States owns a fractional interest.

§ 3120.13 Protests.

(a) No action pursuant to the regulations in this subpart will be suspended under 43 CFR 4.21(a) due to a protest from a notice by the authorized officer to hold a lease sale.

(b) Notwithstanding paragraph (a) of this section, the authorized officer may suspend the offering of a specific parcel while considering a protest against its inclusion in a Notice of Competitive Lease Sale.

(c) Only the Assistant Secretary for Land and Minerals Management may suspend a lease sale for good cause after reviewing the reason(s) for a protest.

Lease Terms

§ 3120.21 Duration of lease.

Competitive leases will be issued for a primary term of 10 years.

§ 3120.22 Dating of leases.

All competitive leases will be considered issued when signed by the authorized officer. Competitive leases, except future interest leases issued under § 3120.80, will be effective as of the first day of the month following the date the leases are signed on behalf of the United States. A lease may be made effective on the first day of the month within which it is issued if a written request is made prior to the date of signature of the authorized officer. Leases for future interest will be effective as of the date the mineral interests vest in the United States.

§ 3120.23 Lease size.

Lands may be offered in leasing units of not more than 2,560 acres outside Alaska, or 5,760 acres within Alaska, which may be as nearly compact in form as possible.

Expressions of Interest

§ 3120.31 Expression of interest process.

(a) A party submitting an expression of interest in leasing land available for disposition under section 17 of the Mineral Leasing Act must include the submitter's name and address and must submit the expression of interest through the BLM's online leasing system.

(b) The expression must provide a description of the lands identified by legal land description, as follows:

(1) For lands surveyed under the public land survey system, describe the lands to the nearest aliquot part within the legal subdivision, section, township, range, and meridian;

(2) For unsurveyed lands, describe the lands by metes and bounds, giving courses and distances, and tie this information to an official corner of the public land surveys, or to a prominent topographic feature;

(3) For approved protracted surveys, include an entire section, township, range, and meridian. Do not divide protracted sections into aliquot parts;

(4) For lands that have water boundaries, describe the lands based on the initial survey or deed acquiring ownership;

(5) For fractional interest lands, identify the United States mineral ownership by percentage;

(6) For split estate lands, where the surface rights are in private ownership and the rights to develop the oil and gas are managed by the Federal Government, submit the private surface owner's name and address.

(7) For lands where the acquiring agency has assigned an acquisition or tract number covering the lands applied, submit the number in addition to any description otherwise required by this section. If the authorized officer determines that the acquisition or tract number, together with identification of the State and county, constitutes an adequate description, the authorized officer may allow the description in this manner in lieu of other descriptions required by this section.

(c) A submitter may submit more than one expression of interest, so long as each expression separately satisfies the requirements of paragraph (b) of this section.

(d) Each expression of interest must include a filing fee, as found in the fee schedule in § 3103.1 of this chapter.

(e) The BLM may offer for sale all or some of the lands specified in an expression of interest and may offer those lands as part of a parcel that includes lands not specified in the expression of interest.

§ 3120.32 Expression of interest leasing preference.

When determining whether the BLM should offer lands specified in an expression of interest at lease sales, the BLM will evaluate the Secretary's obligations to manage public lands for multiple use and sustained yield and to take any action required to prevent unnecessary or undue degradation of the lands and their resources, along with other applicable legal requirements. In evaluating the lands to be offered, as part of the scoping process, the BLM will consider, at minimum:

(a) Proximity to oil and gas development existing at the time of the BLM's evaluation, giving preference to lands upon which a prudent operator would seek to expand existing operations;

(b) The presence of important fish and wildlife habitats or connectivity areas, giving preference to lands that would not impair the proper functioning of such habitats or corridors;

(c) The presence of historic properties, sacred sites, and other high value cultural resources, giving preference to lands that would not impair the cultural significance of such resources;

(d) The presence of recreation and other important uses or resources, giving preference to lands that would not impair the value of such uses or resources; and

(e) The potential for oil and gas development, giving preference to lands with high potential for development.

§ 3120.33 Agency inventory of leasing.

Until August 16, 2032, the BLM will from time to time calculate, for the preceding 1-year period before it issues a wind or solar energy right-of-way, the acreage for which expressions of interest have been submitted to the BLM and the sum total of acres offered for lease.

Notice of Competitive Lease Sale

§ 3120.41 General.

(a) The lands available for competitive lease sale under this subpart will be described in a Notice of Competitive Lease Sale.

(b) The time, date, and place of the competitive lease sale will be stated in the notice.

(c) The notice will include an identification of, and a copy of, stipulations applicable to each parcel.

§ 3120.42 Posting timeframes.

(a) After identifying a preliminary list of lands for a lease sale, the BLM will provide a scoping period, of not less than 30 calendar days, for public comment on the preliminary parcel list for the upcoming lease sale. The preliminary parcel list is not subject to protests or appeals.

(b) After drafting a National Environmental Policy Act document for a lease sale, the BLM will provide a comment period, of not less than 30 calendar days, for public comment on the National Environmental Policy Act document for the upcoming lease sale. The draft National Environmental Policy Act document is not subject to protests or appeals.

(c) At least 60 calendar days prior to conducting a competitive auction, the BLM will make available to the public a list of lands to be offered for competitive lease sale in a Notice of Competitive Lease Sale.

(d) After posting the Notice of Competitive Lease Sale notice, the BLM will provide a protest period, of not less than 30 calendar days, for public input on the upcoming lease sale.

(e) The BLM will make available the final National Environmental Policy Act compliance documents prior to issuing a lease from the lease sale.

Competitive Auction

§ 3120.51 Competitive auction.

(a) Parcels will be offered by competitive auction.

(b) A winning bid will be the highest bid by a responsible and qualified bidder, equal to or exceeding the national minimum acceptable bid. The decision of the auctioneer will be final.

§ 3120.52 Payments required.

(a) Payments must be made in accordance with 43 CFR 3103.11.

(b) Each winning bidder must submit, by the close of official business hours on

the day of the sale for the parcel, or such other time as may be specified by the authorized officer:

(1) The minimum bonus bid as specified in § 3103.1 of this chapter;

(2) The total amount of the first year's rental; and

(3) The processing fee for competitive lease applications found in the fee schedule in § 3000.120 of this chapter for each parcel.

(c) The winning bidder must submit the balance of the bonus bid to the proper BLM office within 10 business days after the last day of the competitive auction.

§ 3120.53 Award of lease.

(a) A bid will not be withdrawn and will constitute a legally binding commitment to execute the lease bid form and accept a lease, including the obligation to pay the bonus bid, first year's rental, and processing fee. Execution by the high bidder of a competitive lease bid form approved by the Director constitutes certification of compliance with 43 CFR subpart 3102, will constitute a binding lease offer, including all terms and conditions applicable thereto, and must be submitted when payment is made in accordance with § 3120.62(b). Failure to comply with § 3120.62(c) will result in rejection of the bid and forfeiture of the monies submitted under § 3120.62(b).

(b) A lease will be awarded to the highest responsible and qualified bidder. A copy of the lease will be provided to the lessee after signature by the authorized officer.

(c) If a bid is rejected, the land may be reoffered competitively under this subpart.

(d) The BLM will not issue a lease until it resolves all protests covering the lands to be leased.

(e) Leases will be issued within 60 calendar days, following payment by the successful bidder of the remainder of the bonus bid, if any, and the annual rental for the first lease year. If the BLM cannot issue the lease within 60 days, the BLM, with the consent of the bidder, may reject the offer.

§ 3120.60 Parcels not bid on at auction.

Lands offered at the competitive auction that received no bids may be offered in a future competitive auction.

Future Interest

§ 3120.71 Expression of interest to make lands available for competitive lease.

An expression of interest for a future interest lease must be filed in accordance with this subpart.

§ 3120.72 Future interest terms and conditions.

(a) No rental or royalty will be due to the United States prior to the vesting of the oil and gas rights in the United States. However, the future interest lessee must agree that if, he/she is or becomes the holder of any present interest operating rights in the lands:

(1) The future interest lessee transfers all or a part of the lessee's present oil and gas interests, such lessee must file in the proper BLM office an assignment or transfer, in accordance with 43 CFR subpart 3106, of the future interest lease of the same type and proportion as the transfer of the present interest; and

(2) The future interest lessee's present lease interests are relinquished, cancelled, terminated, or expired, the future interest lease rights with the United States also will cease and terminate to the same extent.

(b) Upon vesting of the oil and gas rights in the United States, the future interest lease rental and royalty will be as for any competitive lease issued under this subpart, as provided in 43 CFR subpart 3103, and the acreage will be chargeable in accordance with 43 CFR 3101.20.

§ 3120.73 Compensatory royalty agreements.

The terms and conditions of compensatory royalty agreements involving acquired lands in which the United States owns a future or fractional interest will be established on an individual case basis. Such agreements may be required when leasing is not possible in situations where the interest of the United States in the oil and gas deposit includes both a present and a future fractional interest in the same tract containing a producing well.

PART 3130—OIL AND GAS LEASING: NATIONAL PETROLEUM RESERVE ALASKA

■ 5. The authority citation for part 3130 continues to read as follows:

Authority: 42 U.S.C. 6508, 43 U.S.C. 1733 and 1740.

■ 6. Revise § 3137.23 to read as follows:

§ 3137.23 NPR–A unitization application.

The unitization application must include:

(a) The proposed unit agreement;

(b) A map showing the proposed unit area;

(c) A list of committed tracts including, for each tract, the:

(1) Legal land description and acreage;

(2) Names of persons holding record title interest;

(3) Names of persons owning operating rights; and

(4) Name of the unit operator.

(d) A statement certifying:

(1) The operator invited all owners of oil and gas rights (leased or unleased) and lease interests (record title and operating rights) within the external boundary of the unit area described in the application to join the unit;

(2) That there are sufficient tracts committed to the unit agreement to reasonably operate and develop the unit area;

(3) The commitment status of all tracts within the area proposed for unitization; and

(4) The operator accepts unit obligations under § 3137.60 of this subpart.

(e) Evidence of acceptable bonding;

(f) A discussion of reasonably foreseeable and significantly adverse effects on the surface resources of the NPR–A and how unit operations may reduce impacts compared to individual lease operations;

(g) A discussion of the proposed methodology for allocating production among the committed tracts. If the unit includes non-Federal oil and gas mineral estate, you must explain how the methodology takes into account reservoir heterogeneity and area variation in reservoir producibility; and

(h) Other documentation that the BLM may request. The BLM may require additional copies of maps, plats, and other similar exhibits.

(i) The processing fee found in the fee schedule in § 3000.120 of this chapter.

■ 7. Revise § 3137.61 to read as follows:

§ 3137.61 Change in unit operators.

(a) To change unit operators, the new unit operator must submit to the BLM:

(1) Statements that:

(i) The new operator accepts unit obligations; and

(ii) The percentage of required interest owners consented to a change of unit operator;

(2) Evidence of acceptable bonding (*see* § 3137.60(b)); and

(3) The processing fee found in the fee schedule in § 3000.120 of this chapter.

(b) The effective date of the change in unit operator is the date the BLM approves the new unit operator.

■ 8. Revise § 3138.11 to read as follows:

§ 3138.11 Applications for a subsurface storage agreement.

(a) An application for a subsurface storage agreement must include:

(1) The reason for forming a subsurface storage agreement;

(2) A description of the area to be included in the subsurface storage agreement;

(3) A description of the formation to be used for storage;

(4) The proposed storage fees or rentals. The fees or rentals must be based on the value of the subsurface storage, injection, and withdrawal volumes, and rental income or other income generated by the operator for letting or subletting the storage facilities;

(5) The payment of royalty for native oil or gas (oil or gas that exists in the formation before injection and that is produced when the stored oil or gas is withdrawn);

(6) A description of how often and under what circumstances the operator and the BLM intend to renegotiate fees and payments;

(7) The proposed effective date and term of the subsurface storage agreement;

(8) Certification that all owners of mineral rights (leased or unleased) and lease interests have consented to the gas storage agreement in writing;

(9) An ownership schedule showing lease or land status;

(10) A schedule showing the participation factor for all parties to the subsurface storage agreement;

(11) Supporting data (geologic maps showing the storage formation, reservoir data, etc.) demonstrating the capability of the reservoir for storage; and

(12) The processing fee found in the fee schedule in § 3000.120 of this chapter.

(b) The BLM will negotiate the terms of a subsurface storage agreement with the operator, including bonding, and reservoir management.

(c) The BLM may request documentation in addition to that which the operator provides under paragraph (a) of this section.

■ 9. Revise part 3140 to read as follows:

PART 3140—LEASING IN SPECIAL TAR SAND AREAS

Subpart 3140—Conversion of Existing Oil and Gas Leases and Valid Claims Based on Mineral Locations

Sec.

PART 3140—LEASING IN SPECIAL TAR SAND AREAS

Authority: 30 U.S.C. 181 *et seq.;* 30 U.S.C. 351–359; 43 U.S.C. 1701 *et seq.;* Pub. L. 97–78, 95 Stat. 1070; 42 U.S.C. 15801, unless otherwise noted.

Subpart 3140—Conversion of Existing Oil and Gas Leases and Valid Claims Based on Mineral Locations

§ 3140.1 Purpose.

The purpose of this subpart is to provide for the conversion of existing oil and gas leases and valid claims based on mineral locations within Special Tar Sand Areas to combined hydrocarbon leases.

§ 3140.3 Authority.

These regulations are issued under the authority of the Mineral Lands Leasing Act of February 25, 1920 (30 U.S.C. 181 *et seq.*), the Mineral Leasing Act for Acquired Lands (30 U.S.C. 351 *et seq.*), and the Combined Hydrocarbon Leasing Act of 1981 (Pub. L. 97–78).

§ 3140.5 Definitions.

As used in this subpart, the term:

Combined hydrocarbon lease means a lease issued in a Special Tar Sand Area for the removal of gas and nongaseous hydrocarbon substances other than coal, oil shale or gilsonite.

Complete plan of operations means a plan of operations that is in substantial compliance with the information requirements of 43 CFR part 3592 for both exploration plans and mining plans, as well as any additional information required in this part and under 43 CFR part 3593, as may be appropriate.

Owner of an oil and gas lease means all of the record title holders of an oil and gas lease.

Owner of a valid claim based on a mineral location means all parties appearing on the title records recognized as official under State law as having the right to sell or transfer any part of the mining claim, which was located within a Special Tar Sand Area prior to January 21, 1926, for any hydrocarbon resource, except coal, oil shale or gilsonite, leasable under the Combined Hydrocarbon Leasing Act.

Special Tar Sand Area means an area designated by the Department of the Interior's orders of November 20, 1980 (45 FR 76800), and January 21, 1981 (46 FR 6077) referred to in those orders as Designated Tar Sand Areas, as containing substantial deposits of tar sand.

Unitization means unitization as that term is defined in 43 CFR part 3180.

General Provisions

§ 3140.11 Existing rights.

(a) The owner of an oil and gas lease issued prior to November 16, 1981, or the owner of a valid claim based on a mineral location situated within a Special Tar Sand Area may convert that portion of the lease or claim so situated to a combined hydrocarbon lease, provided that such conversion is consistent with the provisions of this subpart. The application time period ended on November 15, 1983.

(b) Owners of oil and gas leases in Special Tar Sand Areas who elect not to convert their leases to a combined hydrocarbon lease do not acquire the rights to any hydrocarbon resource except oil and gas as those terms were defined prior to the enactment of the Combined Hydrocarbon Leasing Act of 1981. The failure to file an application to convert a valid claim based on a mineral location within the time herein provided will have no effect on the validity of the mining claim nor the right to maintain that claim.

§ 3140.12 Notice of intent to convert.

(a) Owners of oil and gas leases in Special Tar Sand Areas which were scheduled to expire prior to November 15, 1983, could have preserved the right to convert their leases to combined hydrocarbon leases by filing a Notice of Intent to Convert with the BLM Utah State Office.

(b) A letter, submitted by the lessee, notifying the BLM of the lessee's intention to submit a plan of operations constituted a notice of intent to convert a lease. The Notice of Intent must have contained the lease number.

(c) The Notice of Intent must have been filed prior to the expiration date of the lease. The notice would have preserved the lessee's conversion rights only until November 15, 1983.

§ 3140.13 Exploration plans.

(a) The authorized officer may grant permission to holders of existing oil and gas leases to gather information to develop, perfect, complete or amend a plan of operations required for conversion upon the approval of the authorized officer of an exploration plan developed in accordance with 43 CFR 3592.1.

(b) The approval of an exploration plan in units of the National Park System requires the consent of the Regional Director of the National Park Service in accordance with § 3140.70.

(c) The filing of an exploration plan alone will be insufficient to meet the requirements of a complete plan of operations as set forth in § 3140.23.

§ 3140.14 Other provisions.

(a) A combined hydrocarbon lease will be for no more than 5,760 acres. Acreage held under a combined hydrocarbon lease in a Special Tar Sand Area is not chargeable to State oil and gas limitations allowable in 43 CFR 3101.21 or 3101.22.

(b) The annual rental rate for all combined hydrocarbon leases will be as stated in the lease, and the annual rental for all new leases will be as specified in 43 CFR 3103.1. The rental rate for a combined hydrocarbon lease will be payable upon conversion and annually, in advance, thereafter.

(c)(1) The royalty rate for a combined hydrocarbon lease converted from an oil and gas lease will be that provided for in the original oil and gas lease.

(2) The royalty rate for a combined hydrocarbon lease converted from a valid claim based on a mineral location will be 16.67 percent.

(3) A reduction of royalties may be granted either as provided in § 3103.40 or, at the request of the lessee and upon a review of information provided by the lessee, prior to commencement of commercial operations if the purpose of the request is to promote development and the maximum production of tar sand. A reduction of royalties for the tar sand will not apply to the oil and gas resource. A reduction of royalties for the oil and gas will not apply to the tar sand resource.

(d)(1) Existing oil and gas leases and valid claims based on mineral locations may be unitized prior to or after the lease or claim has been converted to a combined hydrocarbon lease. The requirements of 43 CFR part 3180 will provide the procedures and general guidelines for unitization of combined hydrocarbon leases. For leases within units of the National Park System, unitization requires the consent of the Regional Director of the National Park Service in accordance with § 3140.41(b).

(2) If the plan of operations submitted for conversion is designed to cover a unit, a fully executed unit agreement will be approved before the plan of operations applicable to the unit may be approved under § 3140.20. The proposed plan of operations and the proposed unit agreement may be reviewed concurrently. The approved unit agreement will be effective after the leases or claims subject to it are converted to combined hydrocarbon leases. The plan of operations will explain how and when each lease included in the unit operation will be developed.

(e) Except as provided for in this subpart, the regulations set out in 43 CFR part 3100 are applicable, as appropriate, to all combined hydrocarbon leases issued under this subpart.

Applications

§ 3140.21 Forms.

No special form is required for a conversion application.

§ 3140.22 Who may apply.

Only owners of oil and gas leases issued within Special Tar Sands Areas, on or before November 16, 1981, and owners of valid claims based on mineral locations within Special Tar Sands Areas, are eligible to convert leases or claims to combined hydrocarbon leases in Special Tar Sands Areas.

§ 3140.23 Application requirements.

(a) The BLM stopped accepting conversion applications on November 15, 1983. The applicant must have submitted to the BLM Utah State Office, a written request for a combined hydrocarbon lease signed by the owner of the lease or valid claim which must be accompanied by three copies of a plan of operations which must meet the requirements of 43 CFR 3592.1 and which must have provided for reasonable protection of the environment and diligent development of the resources requiring enhanced recovery methods of development or mining.

(b) A plan of operations may be modified or amended before or after conversion of a lease or valid claim to reflect changes in technology, slippages in schedule beyond the control of the lessee, new information about the resource or the economic or environmental aspects of its development, changes to or initiation of applicable unit agreements or for other purposes. To obtain approval of a modification or amended plan, the applicant must submit a written statement of the proposed changes or supplements and the justification for the changes proposed. Any modifications will be in accordance with 43 CFR 3592.1(c). The approval of the modification or amendment is the responsibility of the authorized officer. Changes or modification to the plan of operations will have no effect on the primary term of the lease. The authorized officer will, prior to approving any amendment or modification, review the modification or amendment with the appropriate surface management agency. For leases within units of the National Park System, no amendment or modification will be approved without the consent of the Regional Director of the National Park Service in accordance with § 3140.70.

(c) The plan of operations may be for a single existing oil and gas lease or valid claim or for an area of proposed unit operation.

(d) The plan of operations must identify by lease number all Federal oil and gas leases proposed for conversion and identify valid claims proposed for conversion by the recordation number of the mining claim.

(e) The plan of operations must include any proposed designation of

operator or proposed operating agreement.

(f) The plan of operations may include an exploration phase, if necessary, but it must include a development phase. Such a plan can be approved even though it may indicate work under the exploration phase is necessary to perfect the proposed plan for the development phase as long as the overall plan demonstrates reasonable protection of the environment and diligent development of the resources requiring enhanced recovery methods of mining.

(g)(1) Upon determination that the plan of operations is complete, the authorized officer will suspend the term of the Federal oil and gas lease(s) as of the date that the complete plan was filed until the plan is finally approved or rejected. Only the term of the oil and gas lease will be suspended, not any operation and production requirements thereunder.

(2) If the authorized officer determines that the plan of operations is not complete, the applicant will be notified that the plan is subject to rejection if not completed within the period specified in the notice.

(3) The authorized officer may request additional data after the plan of operations has been determined to be complete. This request for additional information will have no effect on the suspension of the running of the oil and gas lease.

Time Limitations

§ 3140.31 Conversion applications.

A plan of operations to convert an existing oil and gas lease or valid claim based on a mineral location to a combined hydrocarbon lease must have been filed on or before November 15, 1983, or prior to the expiration of the oil and gas lease, whichever was earlier, except as provided in § 3140.12.

§ 3140.32 Action on an application.

The authorized officer will take action on an application for conversion within 15 months of receipt of a proposed plan of operations.

Conversion

§ 3140.41 Approval of plan of operations (and unit and operating agreements).

(a) The owner of an oil and gas lease, or the owner of a valid claim based on a mineral location will have such lease or claim converted to a combined hydrocarbon lease when the plan of operations, filed under § 3140.23, is deemed acceptable and is approved by the authorized officer.

(b) The conversion of a lease within a unit of the National Park System will be approved only with the consent of the Regional Director of the National Park Service in accordance with § 3140.70.

(c) A plan of operations may not be approved in part but may be approved where it contains an appropriately staged plan of exploration and development operations.

§ 3140.42 Issuance of the combined hydrocarbon lease.

(a) After a plan of operations is found acceptable, and is approved, the authorized officer will prepare and submit to the owner, for execution, a combined hydrocarbon lease containing all appropriate terms and conditions, including any necessary stipulations that were part of the oil and gas lease being converted, as well as any additional stipulations, such as those required to ensure compliance with the plan of operations.

(b) The authorized officer will not sign the combined hydrocarbon lease until it has been executed by the conversion applicant and the lease or claim to be converted has been formally relinquished to the United States.

(c) The effective date of the combined hydrocarbon lease will be the first day of the month following the date that the authorized officer signs the lease.

(d) The authorized officer will issue one combined hydrocarbon lease to cover the existing contiguous oil and gas leases or valid claims based on mineral locations which have been approved for conversion within the special tar sand area.

§ 3140.50 Duration of the lease.

A combined hydrocarbon lease will be for a primary term of 10 years and for so long thereafter as oil or gas is produced in paying quantities. If the applicant withdraws the combined hydrocarbon lease application or the BLM denies the conversion application, the suspension on the oil and gas lease will be lifted and the term will be extended by the time remaining on the term of the lease.

§ 3140.60 Use of additional lands.

(a) The authorized officer may noncompetitively lease additional lands for ancillary facilities in a Special Tar Sand Area that are needed to support any operations necessary for the recovery of tar sand. Such uses include, but are not limited to, mill site or waste disposal. Application for a lease or permit to use additional lands must be filed under the provisions of 43 CFR part 2920 with the proper BLM office having jurisdiction of the lands. The application for additional lands may be filed at the time a plan of operations is filed.

(b) A lease for the use of additional lands will not be issued when the use can be authorized under 43 CFR parts 2800 and 2880. Such uses include, but are not limited to, reservoirs, pipelines, electrical generation systems, transmission lines, roads, and railroads.

(c) Within units of the National Park System, permits or leases for additional lands will only be issued by the National Park Service. Applications for such permits or leases must be filed with the Regional Director of the National Park Service.

§ 3140.70 Lands within the National Park System.

The BLM stopped accepting conversion applications on November 15, 1983. Conversions of existing oil and gas leases and valid claims based on mineral locations to combined hydrocarbon leases within units of the National Park System will be allowed only where mineral leasing is permitted by law and where the lands covered by the lease or claim proposed for conversion are open to mineral resource disposition in accordance with any applicable minerals management plan. (See 43 CFR 3100.3(h)(4)). In order to consent to any conversion or any subsequent development under a combined hydrocarbon lease requiring further approval, the Regional Director of the National Park Service must find that there will be no resulting significant adverse impacts on the resources and administration of such areas or on other contiguous units of the National Park System in accordance with 43 CFR 3109.20(b).

Subpart 3141—Leasing in Special Tar Sand Areas

§ 3141.1 Purpose.

The purpose of this subpart is to provide for the competitive leasing of lands and issuance of combined hydrocarbon leases, oil and gas leases, or tar sand leases within special tar sand areas.

§ 3141.3 Authority.

The regulations in this subpart are issued under the authority of the Mineral Leasing Act of February 25, 1920 (30 U.S.C. 181 *et seq.*), the Mineral Leasing Act for Acquired Lands (30 U.S.C. 351 *et seq.*), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), the Combined Hydrocarbon Leasing Act of 1981 (95 Stat. 1070), and the Energy Policy Act of 2005 (Pub. L. 109–58).

§ 3141. 5 Definitions.

As used in this subpart, the term:

Combined hydrocarbon lease means a lease issued in a Special Tar Sand Area for the removal of any gas and nongaseous hydrocarbon substance other than coal, oil shale or gilsonite.

Oil and gas lease means a lease issued in a Special Tar Sand Area for the exploration and development of oil and gas resources other than tar sand.

Special Tar Sand Area means an area designated by the Department of the Interior's Orders of November 20, 1980 (45 FR 76800), and January 21, 1981 (46 FR 6077), and referred to in those orders as Designated Tar Sand Areas, as containing substantial deposits of tar sand.

Tar sand means any consolidated or unconsolidated rock (other than coal, oil shale or gilsonite) that either:

(1) Contains a hydrocarbonaceous material with a gas-free viscosity, at original reservoir temperature greater than 10,000 centipoise, or

(2) contains a hydrocarbonaceous material and is produced by mining or quarrying.

Tar sand lease means a lease issued in a Special Tar Sand area exclusively for the exploration for and extraction of tar sand.

§ 3141.8 Other applicable regulations.

(a) *Combined hydrocarbon leases.* (1) The following provisions of 43 CFR part 3100, as they relate to competitive leasing, apply to the issuance and administration of combined hydrocarbon leases issued under this part.

(i) All of 43 CFR subpart 3100;

(ii) All of 43 CFR subpart 3101, with the exception of §§ 3101.21, 3101.22, 3101.23, 3101.24, and 3101.25;

(iii) All of 43 CFR subpart 3102;

(iv) All of 43 CFR subpart 3103, with the exception of §§ 3103.21, and 3103.31(a), (b), and (c);

(v) All of 43 CFR subpart 3104;

(vi) All of 43 CFR subpart 3105;

(vii) All of 43 CFR subpart 3106, with the exception of § 3106.10(j);

(viii) All of 43 CFR subpart 3107;

(ix) All of 43 CFR subpart 3108; and

(x) All of 43 CFR subpart 3109, with special emphasis on § 3109.20(b).

(2) Prior to commencement of operations, the lessee must develop either a plan of operations as described in 43 CFR 3592.1 which ensures reasonable protection of the environment or file an application for a permit to drill as described in 43 CFR part 3160, whichever is appropriate.

(3) The provisions of 43 CFR part 3180 will serve as general guidance to the administration of combined hydrocarbon leases issued under this part to the extent they may be included in unit or cooperative agreements.

(b) *Oil and gas leases.* (1) All of the provisions of 43 CFR parts 3100, and 3120 apply to the issuance and administration of oil and gas leases issued under this part.

(2) All of the provisions of 43 CFR parts 3160 and 3170 apply to operations on an oil and gas lease issued under this part.

(3) The provisions of 43 CFR part 3180 apply to the administration of oil and gas leases issued under this part.

(c) *Tar sand leases.* (1) The following provisions of 43 CFR part 3100, as they relate to competitive leasing, apply to the issuance of tar sand leases issued under this part.

(i) All of 43 CFR subpart 3102;

(ii) All of 43 CFR subpart 3103 with the exception of §§ 3103.21, 3103.22(d), 3103.31, and 3103.32;

(iii) All of 43 CFR 3120.50; and

(iv) All of 43 CFR 3120.60.

(2) Prior to commencement of operations, the lessee must develop a plan of operations as described in 43 CFR 3592.1 which ensures reasonable protection of the environment.

§ 3141.10 General.

(a) Combined hydrocarbons or tar sands within a Special Tar Sand Area will be leased only by competitive bonus bidding.

(b) Oil and gas within a Special Tar Sand Area will be leased by competitive bonus bidding as described in 43 CFR part 3120.

(c) The authorized officer may issue either combined hydrocarbon leases, or oil and gas leases for oil and gas within such areas.

(d) The rights to explore for or develop tar sand deposits in a Special Tar Sand Area may be acquired through either a combined hydrocarbon lease or a tar sand lease.

(e) An oil and gas lease in a Special Tar Sand Area does not include the rights to explore for or develop tar sand.

(f) A tar sand lease in a Special Tar Sand Area does not include the rights to explore for or develop oil and gas.

(g) The minimum acceptable bid for a lease issued for tar sand will be as specified in § 3103.1 of this chapter.

(h) The acreage of combined hydrocarbon leases or tar sand leases held within a Special Tar Sand Area will not be charged against acreage limitations for the holding of oil and gas leases as provided in 43 CFR 3101.21.

(i)(1) The authorized officer may noncompetitively lease additional lands for ancillary facilities in a Special Tar Sand Area that are shown by an applicant to be needed to support any operations necessary for the recovery of tar sand. Such uses include, but are not limited to, mill siting or waste disposal. An application for a lease or permit to use additional lands must be filed under the provisions of 43 CFR part 2920 with the proper BLM office having jurisdiction of the lands. The application for additional lands may be filed at the time a plan of operations is filed.

(2) A lease for the use of additional lands will not be issued under this part when the use can be authorized under 43 CFR part 2800. Such uses include, but are not limited to, reservoirs, pipelines, electrical generation systems, transmission lines, roads and railroads.

(3) Within units of the National Park System, permits or leases for additional lands for any purpose will be issued only by the National Park Service. Applications for such permits or leases must be filed with the Regional Director of the National Park Service.

Prelease Exploration Within Special Tar Sand Areas

§ 3141.21 Geophysical exploration.

Geophysical exploration in Special Tar Sand Areas will be governed by 43 CFR part 3150. Information obtained under a permit must be made available to the BLM upon request.

§ 3141.22 Exploration licenses.

(a) Any person(s) responsible and qualified to hold a lease under the provisions of 43 CFR subpart 3102 and this subpart may obtain an exploration license to conduct core drilling and other exploration activities to collect geologic, environmental and other data concerning tar sand resources only on lands, the surface of which are under the jurisdiction of the BLM, within or adjacent to a Special Tar Sand Area. The application for such a license must be submitted to the proper BLM office having jurisdiction over the lands. No drilling for oil or gas will be allowed under an exploration license issued under this subpart. No specific form is required for an application for an exploration license.

(b) The application for an exploration license will be subject to the following requirements:

(1) Each application must contain the name and address of the applicant(s);

(2) Each application must be accompanied by a nonrefundable filing fee based on the coal exploration license application fee found in the fee schedule in § 3000.120 of this chapter;

(3) Each application must contain a description of the lands covered by the application according to section,

township and range in accordance with the official survey;

(4) Each application must include an exploration plan which complies with the requirements of 43 CFR 4392.1(a); and

(5) An application must cover no more than 5,760 acres, which will be as compact as possible. The authorized officer may grant an exploration license covering more than 5,760 acres only if the application contains a justification for an exception to the normal limitation.

(c) The authorized officer may, if the authorized officer determines it necessary to avoid impacts resulting from duplication of exploration activities, require applicants for exploration licenses to provide an opportunity for other parties to participate in exploration under the license on a pro rata cost sharing basis. If joint participation is determined necessary, it will be conducted according to the following:

(1) Immediately upon the notification of a determination that parties will be given an opportunity to participate in the exploration license, the applicant must publish a ''Notice of Invitation,'' approved by the authorized officer, once every week for 2 consecutive weeks in at least one newspaper of general circulation in the area where the lands covered by the exploration license are situated. This notice must contain an invitation to the public to participate in the exploration license on a pro rata cost sharing basis. Copies of the ''Notice of Invitation'' must be filed with the authorized officer at the time of publication by the applicant for posting in the proper BLM office having jurisdiction over the lands covered by the application for at least 30 days prior to the issuance of the exploration license.

(2) Any person seeking to participate in the exploration program described in the Notice of Invitation must notify the authorized officer and the applicant in writing of such intention within 30 days after posting in the proper BLM office having jurisdiction over the lands covered by the Notice of Invitation. The authorized officer may require modification of the original exploration plan to accommodate the legitimate exploration needs of the person(s) seeking to participate and to avoid the duplication of exploration activities in the same area, or that the person(s) should file a separate application for an exploration license.

(3) An application to conduct exploration which could have been conducted under an existing or recent exploration license issued under this paragraph may be rejected.

(d) The authorized officer may accept or reject an exploration license application. An exploration license will become effective on the date specified by the authorized officer as the date when exploration activities may begin. The exploration plan approved by the BLM will be attached and made a part of each exploration license.

(e) An exploration license will be subject to these terms and conditions:

(1) The license will be for a term of not more than 2 years;

(2) The annual rental rate for an exploration license will be as stated in the license;

(3) The licensee must provide a bond in an amount determined by the authorized officer, but not less than $5,000. The authorized officer may accept bonds furnished under 43 CFR subpart 3104, if adequate. The period of liability under the bond will be terminated only after the authorized officer determines that the terms and conditions of the license, the exploration plan and the regulations have been met;

(4) The licensee must provide to the BLM, upon request, all required information obtained under the license. Any information provided will be treated as confidential and proprietary, if appropriate, at the request of the licensee, and will not be made public until the areas involved have been leased or if the BLM determines that public access to the data will not damage the competitive position of the licensee.

(5) Operations conducted under a license will not unreasonably interfere with or endanger any other lawful activity on the same lands, must not damage any improvements on the lands, and will not result in any substantial disturbance to the surface of the lands and their resources;

(6) The authorized officer will include in each license requirements and stipulations to protect the environment and associated natural resources, and to ensure reclamation of the land disturbed by exploration operations;

(7) When unforeseen conditions are encountered that could result in an action prohibited by paragraph (e)(5) of this section, or when warranted by geologic or other physical conditions, the authorized officer may adjust the terms and conditions of the exploration license and may direct adjustment in the exploration plan;

(8) The licensee may submit a request for modification of the exploration plan to the authorized officer. Any modification will be subject to the regulations in this section and the terms and conditions of the license. The authorized officer may approve the modification after any necessary adjustments to the terms and conditions of the license that are accepted in writing by the licensee; and

(9) The license will be subject to termination or suspension as provided in 43 CFR 2920.9–3.

§ 3141.30 Land use plans.

No lease will be issued under this subpart unless the lands have been included in a land use plan which meets the requirements under 43 CFR part 1600 or an approved Minerals Management Plan of the National Park Service. The decision to hold a lease sale and issue leases will be in conformance with the appropriate plan.

Consultation

§ 3141.41 Consultation with the Governor.

The Secretary will consult with the Governor of the State in which any tract proposed for sale is located. The Secretary will give the Governor 30 days to comment before determining whether to conduct a lease sale. The Secretary will seek the recommendations of the Governor of the State in which the lands proposed for lease are located as to whether or not to lease such lands and what alternative actions are available and what special conditions could be added to the proposed lease(s) to mitigate impacts. The Secretary will accept the recommendations of the Governor if the Secretary determines that they provide for a reasonable balance between the national interest and the State's interest. The Secretary will communicate to the Governor in writing and publish in the **Federal Register** the reasons for his/her determination to accept or reject such Governor's recommendations.

§ 3141.42 Consultation with others.

(a) Where the surface is administered by an agency other than the BLM, including lands patented or leased under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*), all leasing under this subpart will be in accordance with the consultation requirements of 43 CFR subpart 3100.

(b) The issuance of combined hydrocarbon leases, oil and gas leases, and tar sand leases within special tar sand areas in units of the National Park System will be allowed only where mineral leasing is permitted by law and where the lands are open to mineral resource disposition in accordance with any applicable Minerals Management Plan. In order to consent to any issuance

of a combined hydrocarbon lease, oil and gas lease, tar sand lease, or subsequent development of hydrocarbon resources within a unit of the National Park System, the Regional Director of the National Park Service will find that there will be no resulting significant adverse impacts to the resources and administration of the unit or other contiguous units of the National Park System in accordance with 43 CFR 3109.20(b).

Leasing Procedures

§ 3141.51 Economic evaluation.

Prior to any lease sale for a combined hydrocarbon lease, the authorized officer will request an economic evaluation of the total hydrocarbon resource on each proposed lease tract exclusive of coal, oil shale, or gilsonite.

§ 3141.52 Term of lease.

(a) Oil and gas leases in special tar sand areas will have a primary term of 10 years and will remain in effect so long thereafter as oil or gas is produced in paying quantities.

(b) Tar Sand leases will have a primary term of 10 years and will remain in effect so long thereafter as tar sand is produced in paying quantities.

§ 3141.53 Royalties and rentals.

(a) The royalty rate on all combined hydrocarbon leases or tar sand leases is 16.67 percent of the value of production removed or sold from a lease. The ONRR will be responsible for collecting and administering royalties.

(b) The lessee may request the Secretary to reduce the royalty rate applicable to a tar sand lease prior to commencement of commercial operations in order to promote development and maximum production of the tar sand resource in accordance with procedures established by the BLM for oil shale leases and may request a reduction in the royalty after commencement of commercial operations in accordance with 43 CFR 3103.41.

(c) The annual rental rate for a combined hydrocarbon lease will be as stated in the lease.

(d) The annual rental rate for a tar sand lease will be as stated in the lease.

(e) Except as explained in paragraphs (a) through (c) of this section, all other provisions of 43 CFR 3103.20 and 3103.30 apply to combined hydrocarbon leasing.

§ 3141.54 Lease size.

Combined hydrocarbon leases or tar sand leases in Special Tar Sand Areas will not exceed 5,760 acres.

§ 3141.55 Dating of lease.

A combined hydrocarbon lease will be effective as of the first day of the month following the date the lease is signed on behalf of the United States, except where a prior written request is made, a lease may be made effective on the first of the month in which the lease is signed.

Sale Procedures

§ 3141.61 Initiation of competitive lease offering.

The BLM may, on its own motion, offer lands through competitive bidding. A request or expression(s) of interest in tract(s) for competitive lease offerings must be submitted in writing to the proper BLM office.

§ 3141.62 Publication of a notice of competitive lease offering.

Combined Hydrocarbon Leases, Tar Sand Leases or Oil and Gas Leases. At least 45 days prior to conducting a competitive auction, lands to be offered for a competitive lease sale, as in a Notice of Competitive Lease Sale, will be made available to the public. The notice will specify the time and place of sale; the manner in which the bids may be submitted; the description of the lands; the terms and conditions of the lease, including the royalty and rental rates; the amount of the minimum bid; and will state that the terms and conditions of the leases are available for inspection and designate the proper BLM office where bid forms may be obtained.

§ 3141.63 Conduct of sales.

(a) *Oil and gas leases.* Lease sales for oil and gas leases will be conducted using the procedures for oil and gas leases in 43 CFR 3120.60.

(b) *Combined hydrocarbon leases and tar sand leases.* (1) Parcels will be offered by competitive auction.

(2) The winning bid will be the highest bid by a responsible and qualified bidder, equal to the minimum bonus bid amount as specified in § 3103.1 of this chapter or for hydrocarbon leases, the minimum bonus bid amount determined under § 3141.51, whichever is larger.

(3) Payments must be made as provided in 43 CFR 3120.62.

§ 3141.64 Qualifications.

Each bidder must submit with the bid a statement over the bidder's signature with respect to compliance with 43 CFR subpart 3102.

§ 3141.65 Rejection of bid.

If the high bid is rejected for failure by the successful bidder to execute the lease forms and pay the balance of the bonus bid, or otherwise to comply with the regulations of this subpart, the minimum bonus payment accompanying the bid will be forfeited.

§ 3141.66 Consideration of next highest bid.

The Department reserves the right to accept the next highest bid if the highest bid is rejected. In no event will an offer be made to the next highest bidder if the difference between that bid and the bid of the rejected successful bidder is greater than the minimum bonus payment forfeited by the rejected successful bidder.

§ 3141.70 Award of lease.

After determining the highest responsible and qualified bidder, the authorized officer will send the lease on a form approved by the Director, and any necessary stipulations, to the successful bidder. The successful bidder must, not later than the 30th calendar day after receipt of the lease, execute the lease, pay the balance of the bid and the first year's rental, and file a bond as required in 43 CFR subpart 3104. Failure to comply with this section will result in rejection of the lease.

Subpart 3142—Paying Quantities/ Diligent Development for Combined Hydrocarbon and Tar Sand Leases

§ 3142.1 Purpose.

This subpart provides definitions and procedures for meeting the production in paying quantities and the diligent development requirements for tar sand in all combined hydrocarbon leases and tar sand leases.

§ 3142.3 Authority.

These regulations are issued under the authority of the Mineral Leasing Act of 1920, as amended and supplemented (30 U.S.C. 181 *et seq.*), the Mineral Leasing Act for Acquired Lands (30 U.S.C. 351–359), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*) and the Combined Hydrocarbon Leasing Act of 1981 (95 Stat. 1070).

§ 3142.5 Definitions.

As used in this subpart, the term:

Production in paying quantities for combined hydrocarbon leases means:

(1) Production, in compliance with an approved plan of operations and by nonconventional methods, of oil and gas which can be marketed; or

(2) Production of oil or gas by conventional methods as the term is currently used in 43 CFR part 3160.

Production in paying quantities for oil and gas leases means production of oil

or gas by conventional methods that meets the definition of ''production in paying quantities'' in 43 CFR 3160.0–5.

Production in paying quantities for tar sand leases means production of shale oil quantities that provide a positive return after all costs of production have been met, including the amortized costs of the capital investment.

§ 3142.10 Diligent development.

A lessee will have met its diligent development obligation if:

(a) The lessee is conducting activity on the lease in accordance with an approved plan of operations; and

(b) The lessee files with the authorized officer, not later than the end of the eighth lease year, a supplement to the approved plan of operations which must include the estimated recoverable tar sand reserves and a detailed development plan for the next stage of operations;

(c) The lessee has achieved production in paying quantities, as that term is defined in § 3142.5(a), by the end of the primary term; and

(d) The lessee annually produces the minimum amount of tar sand established by the authorized officer under the lease in the minimum production schedule which will be made part of the plan of operations or pays annually advance royalty in lieu of this minimum production.

Minimum Production Levels

§ 3142.21 Minimum production schedule.

(a) Upon receipt of the supplement to the plan of operations described in § 3142.10(b), the authorized officer will examine the information furnished by the lessee and determine if the estimate of the recoverable tar sand reserves is adequate and reasonable. In making this determination, the authorized officer may request, and the lessee must furnish, any information that is the basis of the lessee's estimate of the recoverable tar sand reserves. As part of the authorized officer's determination that the estimate of the recoverable tar sand reserves is adequate and reasonable, the authorized officer may consider, but is not limited to, the following: ore grade, strip ratio, vertical and horizontal continuity, extract process recoverability, and proven or unproven status of extraction technology, terrain, environmental mitigation factors, marketability of products and capital operations costs. The authorized officer will then establish as soon as possible, but prior to the beginning of the eleventh year, based upon the estimate of the recoverable tar sand reserves, a minimum annual tar sand production schedule for the lease or unit operations which will start in the eleventh year of the lease. This minimum production level will escalate in equal annual increments to a maximum of 1 percent of the estimated recoverable tar sand reserves in the twentieth year of the lease and remain at 1 percent each year thereafter.

(b) The minimum annual tar sand production schedule for the lease or unit operations will be set at a level for paying quantities. If the operator or lessee cannot establish production in paying quantities, the lease will terminate at the end of the lease's primary term.

§ 3142.22 Advance royalties in lieu of production.

(a) Failure to meet the minimum annual tar sand production schedule level in any year will result in the assessment of an advance royalty in lieu of production which will be credited to future production royalty assessments applicable to the lease or unit.

(b) If there is no production during the lease year, and the lessee has reason to believe that there will be no production during the remainder of the lease year, the lessee must submit to the authorized officer a request for suspension of production at least 90 days prior to the end of that lease year and a payment sufficient to cover any advance royalty due and owing as a result of the failure to produce. Upon receipt of the request for suspension of production and the accompanying payment, the authorized officer may approve a suspension of production for that lease year and the lease will not expire during that year for lack of production.

(c) If there is production on the lease or unit during the lease year, but such production fails to meet the minimum production schedule required by the plan of operations for that lease or unit, the lessee must pay an advance royalty within 60 days of the end of the lease year in an amount sufficient to cover the difference between such actual production and the production schedule required by the plan of operations for that lease or unit and the authorized officer may direct a suspension of production for those periods during which no production occurred.

§ 3142.30 Expiration.

Failure of the lessee to pay advance royalty within the time prescribed by the authorized officer, or failure of the lessee to comply with any other provisions of this subpart following the end of the primary term of the lease, will result in the automatic expiration of the lease as of the first of the month following notice to the lessee of its failure to comply. The lessee will remain subject to the requirement of applicable laws, regulations and lease terms which have not been met at the expiration of the lease.

PART 3150—ONSHORE OIL AND GAS GEOPHYSICAL EXPLORATION

■ 10. The authority citation for part 3150 continues to read as follows:

Authority: 16 U.S.C. 3150(b) and 668dd; 30 U.S.C. 189 and 359; 42 U.S.C. 6508; 43 U.S.C. 1201, 1732(b), 1733, 1734, 1740.

■ 11. Revise subpart 3151 to read as follows:

Subpart 3151—Exploration Outside of Alaska

Subpart 3151—Exploration Outside of Alaska

§ 3151.10 Notice of intent to conduct oil and gas geophysical exploration operations.

Parties wishing to conduct oil and gas geophysical exploration outside of the State of Alaska must file a Notice of Intent to Conduct Oil and Gas Exploration Operations, referred to herein as a notice of intent. The notice of intent must include the filing fee required by 43 CFR 3000.120 and must be filed with the authorized officer of the proper BLM office on the form approved by the Director. Within 5 business days of the filing date, the authorized officer will process the notice of intent and notify the operator of practices and procedures to be followed. If the notice of intent cannot be processed within 5 business days of the filing date, the authorized officer will promptly notify the operator as to when processing will be completed, giving the reason for the delay. The operator must, within 5 business days of the filing date, or such other time as may be convenient for the operator, participate in a field inspection if requested by the authorized officer. Signing of the notice of intent by the operator will signify agreement to comply with the terms and conditions contained therein and in this part, and with all practices and procedures specified at any time by the authorized officer.

§ 3151.20 Notice of completion of operations.

Upon completion of exploration, the permittee must file with the District

Manager a Notice of Completion of Oil and Gas Exploration Operations. Within 30 days after this filing, the authorized officer will notify the permittee whether rehabilitation of the lands is satisfactory or whether additional rehabilitation is necessary, specifying the nature and extent of actions to be taken by the permittee.

§ 3151.30 Collection and submission of data.

(a) The permittee must submit to the authorized officer all data and information obtained in carrying out the exploration plan.

(b) All information submitted under this section is presumptively confidential business information and is subject to 43 CFR part 2, which sets forth the rules of the Department of the Interior relating to public availability of information contained in Departmental records, as provided at § 3100.40 of this chapter.

PART 3160—ONSHORE OIL AND GAS OPERATIONS

■ 12. The authority citation for part 3160 continues to read as follows:

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359, and 1751; 43 U.S.C. 1732(b), 1733, 1740; and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

■ 13. Revise § 3160.0–5 to read as follows:

§ 3160.0–5 Definitions.

As used in this part, the term:

Authorized representative means any entity or individual authorized by the Secretary to perform duties by cooperative agreement, delegation or contract.

Drainage means the migration of hydrocarbons, inert gases (other than helium), or associated resources caused by production from other wells.

Federal lands means all lands and interests in lands owned by the United States which are subject to the mineral leasing laws, including mineral resources or mineral estates reserved to the United States in the conveyance of a surface or nonmineral estate.

Fresh water means water containing not more than 1,000 ppm of total dissolved solids, provided that such water does not contain objectionable levels of any constituent that is toxic to animal, plant or aquatic life, unless otherwise specified in applicable notices or orders.

Knowingly or willfully means a violation that constitutes the voluntary or conscious performance of an act that is prohibited or the voluntary or conscious failure to perform an act or duty that is required. It does not include performances or failures to perform that are honest mistakes or merely inadvertent. It includes, but does not require, performances or failures to perform that result from a criminal or evil intent or from a specific intent to violate the law. The knowing or willful nature of conduct may be established by plain indifference to or reckless disregard of the requirements of the law, regulations, orders, or terms of the lease. A consistent pattern of performance or failure to perform also may be sufficient to establish the knowing or willful nature of the conduct, where such consistent pattern is neither the result of honest mistakes or mere inadvertency. Conduct that is otherwise regarded as being knowing or willful is rendered neither accidental nor mitigated in character by the belief that the conduct is reasonable or legal.

Lease means any contract, profit-share arrangement, joint venture or other agreement issued or approved by the United States under a mineral leasing law that authorizes exploration for, extraction of, or removal of oil or gas.

Lease site means any lands, including the surface of a severed mineral estate, on which exploration for, or extraction and removal of, oil or gas is authorized under a lease.

Lessee means any person holding record title or owning operating rights in a lease issued or approved by the United States.

Lessor means the party to a lease who holds legal or beneficial title to the mineral estate in the leased lands.

Major violation means noncompliance that causes or threatens immediate, substantial, and adverse impacts on public health and safety, the environment, production accountability, or royalty income.

Maximum ultimate economic recovery means the recovery of oil and gas from leased lands which a prudent operator could be expected to make from that field or reservoir given existing knowledge of reservoir and other pertinent facts and utilizing common industry practices for primary, secondary, or tertiary recovery operations.

Minor violation means noncompliance that does not rise to the level of a *major violation.*

New or resumed production under section 102(b)(3) of the Federal Oil and Gas Royalty Management Act means the date on which a well commences production, or resumes production after having been off production for more than 90 days, and is to be construed as follows:

(1) For an oil well, the date on which liquid hydrocarbons are first sold or shipped from a temporary storage facility, such as a test tank, or the date on which liquid hydrocarbons are first produced into a permanent storage facility, whichever first occurs; and

(2) For a gas well, the date on which gas is first measured through sales metering facilities or the date on which associated liquid hydrocarbons are first sold or shipped from a temporary storage facility, whichever first occurs.

Notice to lessees and operators (NTL) means a written notice issued by the authorized officer. NTLs implement the regulations in this part and operating orders, and serve as instructions on specific item(s) of importance within a State, District, or Area.

Onshore oil and gas order means a formal numbered order issued by the Director that implements and supplements the regulations in this part.

Operating rights owner means a person who owns operating rights in a lease. A record title holder may also be an operating rights owner in a lease if it did not transfer all of its operating rights.

Operator means any person or entity including but not limited to the lessee or operating rights owner, who has stated in writing to the authorized officer that it is responsible under the terms and conditions of the lease for the operations conducted on the leased lands or a portion thereof.

Paying well means a well that is capable of producing oil or gas of sufficient value to exceed direct operating costs and the costs of lease rentals or minimum royalty.

Person means any individual, firm, corporation, association, partnership, consortium or joint venture.

Production in paying quantities means production from a lease of oil and/or gas of sufficient value to exceed direct operating costs and the cost of lease rentals or minimum royalties.

Protective well means a well drilled or modified to prevent or offset drainage of oil and gas resources from its Federal or Indian lease.

Record title holder means the person(s) to whom the BLM or an Indian lessor issued a lease or approved the assignment of record title in a lease.

Shut-in well means a nonoperational well that can physically and mechanically operate by opening valves or activating existing equipment.

Superintendent means the superintendent of an Indian Agency, or other officer authorized to act in matters of record and law with respect to oil and gas leases on restricted Indian lands.

Surface use plan of operations means a plan for surface use, disturbance, and reclamation.

Temporarily abandoned well means a nonoperational well that is not physically or mechanically capable of production or injection without additional equipment or without servicing the well, but that may have future beneficial use.

Waste of oil or gas means any act or failure to act by the operator that is not sanctioned by the authorized officer as necessary for proper development and production and which results in:

(1) A reduction in the quantity or quality of oil and gas ultimately producible from a reservoir under prudent and proper operations; or

(2) Avoidable surface loss of oil or gas.

■ 14. Revise § 3162.3–4 to read as follows:

§ 3162.3–4 Well abandonment.

(a) The operator must promptly plug and abandon, in accordance with a plan first approved in writing or prescribed by the authorized officer, each newly completed or recompleted well in which oil or gas is not encountered in paying quantities or which, after being completed as a producing well, is demonstrated to the satisfaction of the authorized officer to be no longer capable of producing oil or gas in paying quantities, unless the authorized officer approves the use of the well as a service well for injection to recover additional oil or gas or for subsurface disposal of produced water. In the case of a newly drilled or recompleted well, the approval to abandon may be written or oral with written confirmation.

(b) Completion of a well as plugged and abandoned may also include conditioning the well as a water supply source for lease operations or for use by the surface owner or appropriate Government Agency, when authorized by the authorized officer. All costs over and above the normal plugging and abandonment expense will be paid by the party accepting the water well.

(c) Upon the removal of drilling or production equipment from the well site which is to be permanently abandoned, the surface of the lands disturbed in connection with the conduct of operations must be reclaimed in accordance with a plan first approved or prescribed by the authorized officer.

(d) Operators of temporarily abandoned wells must:

(1) Receive prior approval from the authorized officer for any well temporarily abandoned for more than 30 days. The authorized officer may authorize a delay in the permanent abandonment of a well for a period of up to 1 year. The operator must provide:

(i) Adequate and detailed justification for the temporary abandonment;

(ii) Verification of the mechanical integrity of the well; and

(iii) Isolate the completed interval(s) prior to temporary abandonment.

(2) Receive prior approval from the authorized officer for any additional delays to permanently abandon a well beyond 1 year. The authorized officer may authorize additional delays, none of which may exceed an additional 1-year period. Each request for additional delay must provide adequate and detailed justification for continued temporary abandonment.

(3) Within 4 years of temporary abandonment of a well, complete one of the following actions:

(i) Permanently abandon the well;

(ii) Resume production in paying quantities or commence using the well for injection or disposal;

(iii) Provide the authorized officer with a detailed plan and timeline for future beneficial use of the well. If the authorized officer determines that there is a legitimate future beneficial use for the well, the officer may allow the operator to delay permanent abandonment by 1 additional year. The authorized officer may grant additional delays in 1-year increments, provided that the operator confirms the future beneficial use of the well and is making verifiable progress on returning the well to a beneficial use.

(e) Operators of shut-in wells must:

(1) Notify the authorized officer of the well's shut-in status, if the well will be shut-in for 90 or more consecutive days, and provide the date the well was shut-in within 90 days of well shut-in;

(2) Within 3 years of well shut-in, provide the authorized officer with verification of the mechanical integrity of the well and confirmation that the well remains capable of producing in paying quantities; and

(3) Within 4 years of well shut-in, complete one of the following actions:

(i) Permanently abandon the well;

(ii) Resume production in paying quantities; or

(iii) Provide the authorized officer with a detailed plan and timeline for future beneficial use of the well. If the authorized officer determines that there is a legitimate future beneficial use for the well, the officer may allow the operator to delay permanent abandonment by 1 year. The authorized officer may grant additional delays in 1-year increments, provided that the operator confirms the future beneficial use of the well and is making verifiable progress on returning the well to a beneficial use.

(f) All wells that are temporarily abandoned or shut-in must have mechanical integrity verified as required in paragraphs (d)(1) and (e)(2) of this section and must ensure that mechanical integrity is verified every 3 years thereafter. The operator must submit the results of each verification of mechanical integrity to the authorized officer within 30 days of the mechanical integrity test.

■ 15. Revise § 3164.1 to read as follows:

§ 3164.1 Onshore Oil and Gas Orders.

(a) The Director is authorized to issue Onshore Oil and Gas Orders when necessary to implement and supplement the regulations in the part. All orders will be published in final form in the **Federal Register**.

(b) These Orders are binding on operating rights owners and operators, as appropriate, of Federal and restricted Indian oil and gas leases which have been, or may hereafter be, issued. There are no current Onshore Oil and Gas Orders currently in effect.

Note: Numbers to be assigned sequentially by the Washington Office as proposed Orders are prepared for publication.

■ 16. Revise § 3165.1 to read as follows:

§ 3165.1 Relief from operating and/or producing requirements.

(a) Applications for relief from either the operating or the producing requirements of a lease, or both, must be filed with the authorized officer, and must include a full statement of the circumstances that render such relief necessary.

(b) The authorized officer will act on applications submitted for a suspension of operations or production, or both, filed pursuant to 43 CFR 3103.42. The application for suspension must be filed with the authorized officer prior to the expiration date of the lease; must be executed by all operating rights owners or by the operator on behalf of the operating rights owners; and must include a full statement of the circumstances that makes such relief necessary.

(c) The authorized officer will not approve an application for a suspension of a lease where the applicant only cites, as the basis for the suspension, a pending application for permit to drill filed less than 90 calendar days prior to the expiration date of the lease.

(d) If approved, a suspension of operations and production will be effective on the first of the month in which the completed application was

filed or the date specified by the authorized officer in the approval. Approved suspensions will not exceed 1 year. If the circumstances warrant all operating rights owners, or the operator on behalf of the operating rights owners, may submit a request to extend the suspension prior to the end of the suspension.

(e) BLM-directed suspensions may exceed 1 year.

(f) Suspensions will lift when the basis provided for the suspension no longer exists, when lifting the suspension is in the public interest, or as otherwise stated by the authorized officer in the approval letter.

PART 3170—ONSHORE OIL AND GAS PRODUCTION

■ 17. The authority citation for part 3170 continues to read as follows:

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359, and 1751; and 43 U.S.C. 1732(b), 1733, and 1740.

■ 18. Revise § 3171.6 to read as follows:

§ 3171.6 Components of a complete APD package.

Operators are encouraged to consider and incorporate Best Management Practices into their APDs because Best Management Practices can result in reduced processing times and reduced number of Conditions of Approval. An APD package must include the following information that will be reviewed by technical specialists of the appropriate agencies to determine the technical adequacy of the package:

(a) A completed Form 3160–3; and

(b) A well plat. Operators must include in the APD package a well plat and geospatial database prepared by a registered surveyor depicting the proposed location of the well and identifying the points of control and datum used to establish the section lines or metes and bounds. The purpose of this plat is to ensure that operations are within the boundaries of the lease or agreement and that the depiction of these operations is accurately recorded both as to location (latitude and longitude) and in relation to the surrounding lease or agreement boundaries (public land survey corner and boundary ties). The registered surveyor should coordinate with the cadastral survey division of the appropriate BLM state office, particularly where the lands have not been surveyed under the Public Land Survey System.

(1) The plat and geospatial database must describe the location of operations in:

(i) Geographical coordinates generated by an electronic navigation system, and document the datum referenced to generate these coordinates; and

(ii) In feet and direction from the nearest two adjacent section lines, or, if not within the Rectangular Survey System, the nearest two adjacent property lines, generated from the BLM's current Geographic Coordinate Data Base.

(2) The surveyor who prepared the plat must sign it, certifying that the location has been staked on the ground as shown on the plat.

(3) Surveying and staking are necessary casual uses, typically involving negligible surface disturbance. The operator is responsible for making access arrangements with the appropriate Surface Managing Agency (other than the BLM and the FS) or private surface owner. On tribal or allotted lands, the operator must contact the appropriate office of the BIA to make access arrangements with the Indian surface owners. In the event that not all of the Indian owners consent or may be located, but a majority of those who can be located consent, or the owners of interests are so numerous that it would be impracticable to obtain their consent and the BIA finds that the issuance of the APD will cause no substantive injury to the land or any owner thereof, the BIA may approve access. Typical off-road vehicular use, when conducted in conjunction with these activities, is a necessary action for obtaining a permit and may be done without advance approval from the Surface Managing Agency, except for:

(i) Lands administered by the Department of Defense;

(ii) Other lands used for military purposes;

(iii) Indian lands; or

(iv) Where more than negligible surface disturbance is likely to occur or is otherwise prohibited.

(4) No entry on split estate lands for surveying and staking should occur without the operator first making a good faith effort to notify the surface owner. Also, operators are encouraged to notify the BLM or the FS, as appropriate, before entering private lands to stake for Federal mineral estate locations.

■ 19. Revise § 3171.14 to read as follows:

§ 3171.14 Valid Period of Approved APD.

(a) For APDs approved after June 22, 2024, an APD approval is valid for 3 years from the date that it is approved, or until lease expiration, whichever occurs first.

(b) Notwithstanding paragraph (a) of this section, if an APD approval expires by reason other than lease expiration, the APD approval shall remain valid if the operator or lessee:

(1) Has drilled the well to the approximate total measured depth in the approved APD, including wells drilled to the approximate total measured depth and not yet completed;

(2) Is drilling the well with a rig capable of drilling the well to the proposed total measured depth in the approved APD; or

(3) Has set the surface casing for the well and has submitted a plan, approved by the BLM prior to expiration of the APD approval, for continuously drilling the well to reach the proposed total measured depth in the approved APD. The plan must include the timeframe for continuously drilling and completing the well and any extenuating circumstances that may delay the continuous drilling and completion of the well.

(c) If, upon expiration of the approved APD, the operator created surface disturbance or began drilling the well under the approved APD, the operator or lessee must either comply with all applicable plugging, abandonment, and reclamation requirements or submit a new APD covering the existing disturbance.

(d) The operator is responsible for reclaiming any surface disturbance that resulted from its actions, even if a well was not drilled. Earthwork for reclamation must be completed within 6 months of APD expiration (weather permitting).

(e) The valid period for an approved APD on a lease suspended under subpart 3103 will be adjusted to account for the suspension. Beginning on the date the suspension is lifted, the valid period of the approved APD will be extended by the time that was remaining on the term of the approved APD on the effective date of the suspension.

PART 3180—ONSHORE OIL AND GAS UNIT AGREEMENTS: UNPROVEN AREAS

■ 20. The authority citation for part 3180 continues to read as follows:

Authority: 30 U.S.C. 189.

§ 3181.1 [Amended]

■ 21. Amend § 3181.1 by removing the phrase ''§ 3186.1 of this title'' wherever it appears and adding in its place the phrase ''appendix A to this part''.

■ 22. Revise § 3181.5 to read as follows:

§ 3181.5 Compensatory royalty payment for unleased Federal land.

The unit agreement submitted by the unit proponent for approval by the authorized officer will provide for payment to the Federal Government of the current royalty percentage for leases offered on onshore oil and gas lease sales on production that would be attributable to unleased Federal lands in a PA of the unit if said lands were leased and committed to the unit agreement. The value of production subject to compensatory royalty payment will be determined pursuant to 30 CFR part 206, provided that no additional royalty will be due on any production subject to compensatory royalty under this provision.

§ 3183.4 [Amended]

■ 23. Amend § 3183.4 in paragraph (a) by removing the phrase ''§ 3186.1 of this title'' and adding in its place the phrase ''appendix A to this part''.

§ 3186.1 [Redesignated as Appendix A to Part 3180]

■ 24. Redesignate § 3186.1 as appendix A to part 3180 and revise it to read as follows:

Appendix A to Part 3180—Model onshore unit agreement for unproven areas.

Introductory Section

Unit Agreement for the Development and Operation of the

Unit area _____
County of _____
State of _____
No. _____

This agreement, entered into as of the ____ day of _____ , 19____ by and between the parties subscribing, ratifying, or consenting hereto, and herein referred to as the ''parties hereto,''

Witnesseth:

Whereas, the parties hereto are the owners of working, royalty, or other oil and gas interests in the unit area subject to this agreement; and

Whereas, the Mineral Leasing Act of February 25, 1920, 41 Stat. 437, as amended, 30 U.S.C. 181 *et seq.,* authorizes Federal lessees and their representatives to unite with each other, or jointly or separately with others, in collectively adopting and operating under a unit plan of development or operations of any oil and gas pool, field, or like area, or any part thereof for the purpose of more properly conserving the natural resources thereof whenever determined and certified by the Secretary of the Interior to be necessary or advisable in the public interest; and

Whereas, the parties hereto hold sufficient interests in the ____ Unit Area covering the land hereinafter described to give reasonably effective control of operations therein; and

Whereas, it is the purpose of the parties hereto to conserve natural resources, prevent waste, and secure other benefits obtainable through development and operation of the area subject to this agreement under the terms, conditions, and limitations herein set forth;

Now, therefore, in consideration of the premises and the promises herein contained, the parties hereto commit to this agreement their respective interests in the below-defined unit area, and agree severally among themselves as follows:

1. ENABLING ACT AND REGULATIONS. The Mineral Leasing Act of February 25, 1920, as amended, supra, and all valid pertinent regulations including operating and unit plan regulations, heretofore issued thereunder or valid, pertinent, and reasonable regulations hereafter issued thereunder are accepted and made a part of this agreement as to Federal lands, provided such regulations are not inconsistent with the terms of this agreement; and as to non-Federal lands, the oil and gas operating regulations in effect as of the effective date hereof governing drilling and producing operations, not inconsistent with the terms hereof or the laws of the State in which the non-Federal land is located, are hereby accepted and made a part of this agreement.

2. UNIT AREA. The area specified on the map attached hereto marked Exhibit A is hereby designated and recognized as constituting the unit area, containing ____ acres, more or less.

Exhibit A shows, in addition to the boundary of the unit area, the boundaries and identity of tracts and leases in said area to the extent known to the Unit Operator. Exhibit B attached hereto is a schedule showing to the extent known to the Unit Operator, the acreage, percentage, and kind of ownership of oil and gas interests in all lands in the unit area. However, nothing herein or in Exhibits A or B shall be construed as a representation by any party hereto as to the ownership of any interest other than such interest or interests as are shown in the Exhibits as owned by such party. Exhibits A and B shall be revised by the Unit Operator whenever changes in the unit area or in the ownership interests in the individual tracts render such revision necessary, or when requested by the Authorized Officer, hereinafter referred to as AO and not less than four copies of the revised Exhibits shall be filed with the proper BLM office.

The above-described unit area shall when practicable be expanded to include therein any additional lands or shall be contracted to exclude lands whenever such expansion or contraction is deemed to be necessary or advisable to conform with the purposes of this agreement. Such expansion or contraction shall be effected in the following manner:

(a) Unit Operator, on its own motion (after preliminary concurrence by the AO), or on demand of the AO, shall prepare a notice of proposed expansion or contraction describing the contemplated changes in the boundaries of the unit area, the reasons therefor, any plans for additional drilling, and the proposed effective date of the expansion or contraction, preferably the first day of a month subsequent to the date of notice.

(b) Said notice shall be delivered to the proper BLM office, and copies thereof mailed to the last known address of each working interest owner, lessee and lessor whose interests are affected, advising that 30 days will be allowed for submission to the Unit Operator of any objections.

(c) Upon expiration of the 30-day period provided in the preceding item (b) hereof, Unit Operator shall file with the AO evidence of mailing of the notice of expansion or contraction and a copy of any objections thereto which have been filed with Unit Operator, together with an application in triplicate, for approval of such expansion or contraction and with appropriate joinders.

(d) After due consideration of all pertinent information, the expansion or contraction shall, upon approval by the AO, become effective as of the date prescribed in the notice thereof or such other appropriate date.

(e) All legal subdivisions of lands (*i.e.,* 40 acres by Government survey or its nearest lot or tract equivalent; in instances of irregular surveys, unusually large lots or tracts shall be considered in multiples of 40 acres or the nearest aliquot equivalent thereof), no parts of which are in or entitled to be in a participating area on or before the fifth anniversary of the effective date of the first initial participating area established under this unit agreement, shall be eliminated automatically from this agreement, effective as of said fifth anniversary, and such lands shall no longer be a part of the unit area and

shall no longer be subject to this agreement, unless diligent drilling operations are in progress on unitized lands not entitled to participation on said fifth anniversary, in which event all such lands shall remain subject hereto for so long as such drilling operations are continued diligently, with not more than 90-days time elapsing between the completion of one such well and the commencement of the next such well. All legal subdivisions of lands not entitled to be in a participating area within 10 years after the effective date of the first initial participating area approved under this agreement shall be automatically eliminated from this agreement as of said tenth anniversary. The Unit Operator shall, within 90 days after the effective date of any elimination hereunder, describe the area so eliminated to the satisfaction of the AO and promptly notify all parties in interest. All lands reasonably proved productive of unitized substances in paying quantities by diligent drilling operations after the aforesaid 5-year period shall become participating in the same manner as during said first 5-year period. However, when such diligent drilling operations cease, all nonparticipating lands not then entitled to be in a participating area shall be automatically eliminated effective as the 91st day thereafter.

Any expansion of the unit area pursuant to this section which embraces lands theretofore eliminated pursuant to this subsection 2(e) shall not be considered automatic commitment or recommitment of such lands. If conditions warrant extension of the 10-year period specified in this subsection, a single extension of not to exceed 2 years may be accomplished by consent of the owners of 90 percent of the working interest in the current nonparticipating unitized lands and the owners of 60 percent of the basic royalty interests (exclusive of the basic royalty interests of the United States) in nonparticipating unitized lands with approval of the AO, provided such extension application is submitted not later than 60 days prior to the expiration of said 10-year period.

3. UNITIZED LAND AND UNITIZED SUBSTANCES. All land now or hereafter committed to this agreement shall constitute land referred to herein as ''unitized land'' or ''land subject to this agreement.'' All oil and gas in any and all formations of the unitized land are unitized under the terms of this agreement and herein are called ''unitized substances.''

4. UNIT OPERATOR. _____ is hereby designated as Unit Operator and by signature hereto as Unit Operator agrees and consents to accept the duties and obligations of Unit Operator for the discovery, development, and production of unitized substances as herein provided. Whenever reference is made herein to the Unit Operator, such reference means the Unit Operator acting in that capacity and not as an owner of interest in unitized substances, and the term ''working interest owner'' when used herein shall include or refer to Unit Operator as the owner of a working interest only when such an interest is owned by it.

5. RESIGNATION OR REMOVAL OF UNIT OPERATOR. Unit Operator shall have the right to resign at any time prior to the establishment of a participating area or areas hereunder, but such resignation shall not become effective so as to release Unit Operator from the duties and obligations of Unit Operator and terminate Unit Operator's rights as such for a period of 6 months after notice of intention to resign has been served by Unit Operator on all working interest owners and the AO and until all wells then drilled hereunder are placed in a satisfactory condition for suspension or abandonment, whichever is required by the AO, unless a new Unit Operator shall have been selected and approved and shall have taken over and assumed the duties and obligations of Unit Operator prior to the expiration of said period.

Unit Operator shall have the right to resign in like manner and subject to like limitations as above provided at any time after a participating area established hereunder is in existence, but in all instances of resignation or removal, until a successor Unit Operator is selected and approved as hereinafter provided, the working interest owners shall be jointly responsible for performance of the duties of Unit Operator, and shall not later than 30 days before such resignation or removal becomes effective appoint a common agent to represent them in any action to be taken hereunder.

The resignation of Unit Operator shall not release Unit Operator from any liability for any default by it hereunder occurring prior to the effective date of its resignation.

The Unit Operator may, upon default or failure in the performance of its duties or obligations hereunder, be subject to removal by the same percentage vote of the owners of working interests as herein provided for the selection of a new Unit Operator. Such removal shall be effective upon notice thereof to the AO.

The resignation or removal of Unit Operator under this agreement shall not terminate its right, title, or interest as the owner of working interest or other interest in unitized substances, but upon the resignation or removal of Unit Operator becoming effective, such Unit Operator shall deliver possession of all wells, equipment, materials, and appurtenances used in conducting the unit operations to the new duly qualified successor Unit Operator or to the common agent, if no such new Unit Operator is selected to be used for the purpose of conducting unit operations hereunder. Nothing herein shall be construed as authorizing removal of any material, equipment, or appurtenances needed for the preservation of any wells.

6. SUCCESSOR UNIT OPERATOR. Whenever the Unit Operator shall tender his or its resignation as Unit Operator or shall be removed as hereinabove provided, or a change of Unit Operator is negotiated by the working interest owners, the owners of the working interests according to their respective acreage interests in all unitized land shall, pursuant to the Approval of the Parties requirements of the unit operating agreement, select a successor Unit Operator. Such selection shall not become effective until:

(a) a Unit Operator so selected shall accept in writing the duties and responsibilities of Unit Operator, and

(b) the selection shall have been approved by the AO.

If no successor Unit Operator is selected and qualified as herein provided, the AO at his election may declare this unit agreement terminated.

7. ACCOUNTING PROVISIONS AND UNIT OPERATING AGREEMENT. If the Unit Operator is not the sole owner of working interests, costs and expenses incurred by Unit Operator in conducting unit operations hereunder shall be paid and apportioned among and borne by the owners of working interests, all in accordance with the agreement or agreements entered into by and between the Unit Operator and the owners of working interests, whether one or more, separately or collectively. Any agreement or agreements entered into between the working interest owners and the Unit Operator as provided in this section, whether one or more, are herein referred to as the ''unit operating agreement.'' Such unit operating agreement shall also provide the manner in which the working interest owners shall be entitled to receive their respective proportionate and allocated share of the benefits accruing hereto in conformity with their underlying operating agreements, leases, or other independent contracts, and such other rights and obligations as between Unit Operator and the working interest owners as may be agreed upon by Unit Operator and the working interest owners; however, no such unit operating agreement shall be deemed either to modify any of the terms and conditions of this unit agreement or to relieve the Unit Operator of any right or obligation established under this unit agreement, and in case of any inconsistency or conflict between this agreement and the unit operating agreement, this agreement shall govern. Two copies of any unit operating agreement executed pursuant to this section shall be filed in the proper BLM office prior to approval of this unit agreement.

8. RIGHTS AND OBLIGATIONS OF UNIT OPERATOR. Except as otherwise specifically provided herein, the exclusive right, privilege, and duty of exercising any and all rights of the parties hereto which are necessary or convenient for prospecting for, producing, storing, allocating, and distributing the unitized substances are hereby delegated to and shall be exercised by the Unit Operator as herein provided. Acceptable evidence of title to said rights shall be deposited with Unit Operator and, together with this agreement, shall constitute and define the rights, privileges, and obligations of Unit Operator. Nothing herein, however, shall be construed to transfer title to any land or to any lease or operating agreement, it being understood that under this agreement the Unit Operator, in its capacity as Unit Operator, shall exercise the rights of possession and use vested in the parties hereto only for the purposes herein specified.

9. DRILLING TO DISCOVERY. Within 6 months after the effective date hereof, the Unit Operator shall commence to drill an

adequate test well at a location approved by the AO, unless on such effective date a well is being drilled in conformity with the terms hereof, and thereafter continue such drilling diligently until the ____ formation has been tested or until at a lesser depth unitized substances shall be discovered which can be produced in paying quantities (to wit: quantities sufficient to repay the costs of drilling, completing, and producing operations, with a reasonable profit) or the Unit Operator shall at any time establish to the satisfaction of the AO that further drilling of said well would be unwarranted or impracticable, provided, however, that Unit Operator shall not in any event be required to drill said well to a depth in excess of ____ feet. Until the discovery of unitized substances capable of being produced in paying quantities, the Unit Operator shall continue drilling one well at a time, allowing not more than 6 months between the completion of one well and the commencement of drilling operations for the next well, until a well capable of producing unitized substances in paying quantities is completed to the satisfaction of the AO or until it is reasonably proved that the unitized land is incapable of producing unitized substances in paying quantities in the formations drilled hereunder. Nothing in this section shall be deemed to limit the right of the Unit Operator to resign as provided in Section 5, hereof, or as requiring Unit Operator to commence or continue any drilling during the period pending such resignation becoming effective in order to comply with the requirements of this section.

The AO may modify any of the drilling requirements of this section by granting reasonable extensions of time when, in his opinion, such action is warranted.

[2] 9a. MULTIPLE WELL REQUIREMENTS. Notwithstanding anything in this unit agreement to the contrary, except Section 25, UNAVOIDABLE DELAY, ____ wells shall be drilled with not more than 6-months time elapsing between the completion of the first well and commencement of drilling operations for the second well and with not more than 6-months time elapsing between completion of the second well and the commencement of drilling operations for the third well, . . . regardless of whether a discovery has been made in any well drilled under this provision. Both the initial well and the second well must be drilled in compliance with the above specified formation or depth requirements in order to meet the dictates of this section; and the second well must be located a minimum of ____ miles from the initial well in order to be accepted by the AO as the second unit test well, within the meaning of this section. The third test well shall be diligently drilled, at a location approved by the AO, to test the ____ formation or to a depth of ____ feet, whichever is the lesser, and must be located a minimum of ____ miles from both the initial and the second test wells. Nevertheless, in the event of the discovery of unitized substances in paying quantities by any well, this unit agreement shall not terminate for failure to complete the ____ well program, but the unit area shall be contracted automatically, effective the first day of the month following the default, to eliminate by subdivisions (as defined in Section 2(e) hereof) all lands not then entitled to be in a participating area.

Until the establishment of a participating area, the failure to commence a well subsequent to the drilling of the initial obligation well, or in the case of multiple well requirements, if specified, subsequent to the drilling of those multiple wells, as provided for in this (these) section(s), within the time allowed including any extension of time granted by the AO, shall cause this agreement to terminate automatically. Upon failure to continue drilling diligently any well other than the obligation well(s) commenced hereunder, the AO may, after 15-days' notice to the Unit Operator, declare this unit agreement terminated. Failure to commence drilling the initial obligation well, or the first of multiple obligation wells, on time and to drill it diligently shall result in the unit agreement approval being declared invalid *ab initio* by the AO. In the case of multiple well requirements, failure to commence drilling the required multiple wells beyond the first well, and to drill them diligently, may result in the unit agreement approval being declared invalid *ab initio* by the AO;

10. PLAN OF FURTHER DEVELOPMENT AND OPERATION. Within 6 months after completion of a well capable of producing unitized substances in paying quantities, the Unit Operator shall submit for the approval of the AO an acceptable plan of development and operation for the unitized land which, when approved by the authorized officer, shall constitute the further drilling and development obligations of the Unit Operator under this agreement for the period specified therein. Thereafter, from time to time before the expiration of any existing plan, the Unit Operator shall submit for the approval of the AO a plan for an additional specified period for the development and operation of the unitized land. Subsequent plans should normally be filed on a calendar year basis not later than March 1 each year. Any proposed modification or addition to the existing plan should be filed as a supplement to the plan.

Any plan submitted pursuant to this section shall provide for the timely exploration of the unitized area, and for the diligent drilling necessary for determination of the area or areas capable of producing unitized substances in paying quantities in each and every productive formation. This plan shall be as complete and adequate as the AO may determine to be necessary for timely development and proper conservation of the oil and gas resources in the unitized area and shall:

(a) Specify the number and locations of any wells to be drilled and the proposed order and time for such drilling; and

(b) Provide a summary of operations and production for the previous year.

Plans shall be modified or supplemented when necessary to meet changed conditions or to protect the interests of all parties to this agreement. Reasonable diligence shall be exercised in complying with the obligations of the approved plan of development and operation. The AO is authorized to grant a reasonable extension of the 6-month period herein prescribed for submission of an initial plan of development and operation where such action is justified because of unusual conditions or circumstances.

After completion of a well capable of producing unitized substances in paying quantities, no further wells, except such as may be necessary to afford protection against operations not under this agreement and such as may be specifically approved by the AO, shall be drilled except in accordance with an approved plan of development and operation.

11. PARTICIPATION AFTER DISCOVERY. Upon completion of a well capable of producing unitized substances in paying quantities, or as soon thereafter as required by the AO, the Unit Operator shall submit for approval by the AO, a schedule, based on subdivisions of the public-land survey or aliquot parts thereof, of all land then regarded as reasonably proved to be productive of unitized substances in paying quantities. These lands shall constitute a participating area on approval of the AO, effective as of the date of completion of such well or the effective date of this unit agreement, whichever is later. The acreages of both Federal and non-Federal lands shall be based upon appropriate computations from the courses and distances shown on the last approved public-land survey as of the effective date of each initial participating area. The schedule shall also set forth the percentage of unitized substances to be allocated, as provided in Section 12, to each committed tract in the participating area so established, and shall govern the allocation of production commencing with the effective date of the participating area. A different participating area shall be established for each separate pool or deposit of unitized substances or for any group thereof which is produced as a single pool or zone, and any two or more participating areas so established may be combined into one, on approval of the AO. When production from two or more participating areas is subsequently found to be from a common pool or deposit, the participating areas shall be combined into one, effective as of such appropriate date as may be approved or prescribed by the AO. The participating area or areas so established shall be revised from time to time, subject to the approval of the AO, to include additional lands then regarded as reasonably proved to be productive of unitized substances in paying quantities or which are necessary for unit operations, or to exclude lands then regarded as reasonably proved not to be productive of unitized substances in paying quantities, and the schedule of allocation percentages shall be revised accordingly. The effective date of any revision shall be the first of the month in which the knowledge or information is obtained on which such revision is predicated; provided, however, that a more appropriate effective date may be used if justified by Unit Operator and approved by the AO. No land shall be excluded from a participating area on account of depletion of its unitized substances, except that any participating area established under the provisions of this unit agreement shall terminate automatically whenever all

completions in the formation on which the participating area is based are abandoned.

It is the intent of this section that a participating area shall represent the area known or reasonably proved to be productive of unitized substances in paying quantities or which are necessary for unit operations; but, regardless of any revision of the participating area, nothing herein contained shall be construed as requiring any retroactive adjustment for production obtained prior to the effective date of the revision of the participating area.

In the absence of agreement at any time between the Unit Operator and the AO as to the proper definition or redefinition of a participating area, or until a participating area has, or areas have, been established, the portion of all payments affected thereby shall, except royalty due the United States, be impounded in a manner mutually acceptable to the owners of committed working interests. Royalties due the United States shall be determined by the AO and the amount thereof shall be deposited, as directed by the AO, until a participating area is finally approved and then adjusted in accordance with a determination of the sum due as Federal royalty on the basis of such approved participating area.

Whenever it is determined, subject to the approval of the AO, that a well drilled under this agreement is not capable of production of unitized substances in paying quantities and inclusion in a participating area of the land on which it is situated is unwarranted, production from such well shall, for the purposes of settlement among all parties other than working interest owners, be allocated to the land on which the well is located, unless such land is already within the participating area established for the pool or deposit from which such production is obtained. Settlement for working interest benefits from such a nonpaying unit well shall be made as provided in the unit operating agreement.

12. ALLOCATION OF PRODUCTION. All unitized substances produced from a participating area established under this agreement, except any part thereof used in conformity with good operating practices within the unitized area for drilling, operating, and other production or development purposes, or for repressuring or recycling in accordance with a plan of development and operations that has been approved by the AO, or unavoidably lost, shall be deemed to be produced equally on an acreage basis from the several tracts of unitized land and unleased Federal land, if any, included in the participating area established for such production. Each such tract shall have allocated to it such percentage of said production as the number of acres of such tract included in said participating area bears to the total acres of unitized land and unleased Federal land, if any, included in said participating area. There shall be allocated to the working interest owner(s) of each tract of unitized land in said participating area, in addition, such percentage of the production attributable to the unleased Federal land within the participating area as the number of acres of such unitized tract included in said participating area bears to the total acres of unitized land in said participating area, for the payment of the compensatory royalty specified in section 17 of this agreement. Allocation of production hereunder for purposes other than for settlement of the royalty, overriding royalty, or payment out of production obligations of the respective working interest owners, including compensatory royalty obligations under section 17, shall be prescribed as set forth in the unit operating agreement or as otherwise mutually agreed by the affected parties. It is hereby agreed that production of unitized substances from a participating area shall be allocated as provided herein, regardless of whether any wells are drilled on any particular part or tract of the participating area. If any gas produced from one participating area is used for repressuring or recycling purposes in another participating area, the first gas withdrawn from the latter participating area for sale during the life of this agreement shall be considered to be the gas so transferred, until an amount equal to that transferred shall be so produced for sale and such gas shall be allocated to the participating area from which initially produced as such area was defined at the time that such transferred gas was finally produced and sold.

13. DEVELOPMENT OR OPERATION OF NONPARTICIPATING LAND OR FORMATIONS. Any operator may with the approval of the AO, at such party's sole risk, costs, and expense, drill a well on the unitized land to test any formation provided the well is outside any participating area established for that formation, unless within 90 days of receipt of notice from said party of his intention to drill the well, the Unit Operator elects and commences to drill the well in a like manner as other wells are drilled by the Unit Operator under this agreement.

If any well drilled under this section by a non-unit operator results in production of unitized substances in paying quantities such that the land upon which it is situated may properly be included in a participating area, such participating area shall be established or enlarged as provided in this agreement and the well shall thereafter be operated by the Unit Operator in accordance with the terms of this agreement and the unit operating agreement.

If any well drilled under this section by a non-unit operator that obtains production in quantities insufficient to justify the inclusion of the land upon which such well is situated in a participating area, such well may be operated and produced by the party drilling the same, subject to the conservation requirements of this agreement. The royalties in amount or value of production from any such well shall be paid as specified in the underlying lease and agreements affected.

14. ROYALTY SETTLEMENT. The United States and any State and any royalty owner who is entitled to take in kind a share of the substances now unitized hereunder shall be hereafter be entitled to the right to take in kind its share of the unitized substances, and Unit Operator, or the non-unit operator in the case of the operation of a well by a non-unit operator as herein provided for in special cases, shall make deliveries of such royalty share taken in kind in conformity with the applicable contracts, laws, and regulations. Settlement for royalty interest not taken in kind shall be made by an operator responsible therefor under existing contracts, laws and regulations, or by the Unit Operator on or before the last day of each month for unitized substances produced during the preceding calendar month; provided, however, that nothing in this section shall operate to relieve the responsible parties of any land from their respective lease obligations for the payment of any royalties due under their leases.

If gas obtained from lands not subject to this agreement is introduced into any participating area hereunder, for use in repressuring, stimulation of production, or increasing ultimate recovery, in conformity with a plan of development and operation approved by the AO, a like amount of gas, after settlement as herein provided for any gas transferred from any other participating area and with appropriate deduction for loss from any cause, may be withdrawn from the formation into which the gas is introduced, royalty free as to dry gas, but not as to any products which may be extracted therefrom; provided that such withdrawal shall be at such time as may be provided in the approved plan of development and operation or as may otherwise be consented to by the AO as conforming to good petroleum engineering practice; and provided further, that such right of withdrawal shall terminate on the termination of this unit agreement.

Royalty due the United States shall be computed as provided in 30 CFR Group 200 and paid in value or delivered in kind as to all unitized substances on the basis of the amounts thereof allocated to unitized Federal land as provided in Section 12 at the rates specified in the respective Federal leases, or at such other rate or rates as may be authorized by law or regulation and approved by the AO; provided, that for leases on which the royalty rate depends on the daily average production per well, said average production shall be determined in accordance with the operating regulations as though each participating area were a single consolidated lease.

15. RENTAL SETTLEMENT. Rental or minimum royalties due on leases committed hereto shall be paid by the appropriate parties under existing contracts, laws, and regulations, provided that nothing herein contained shall operate to relieve the responsible parties of the land from their respective obligations for the payment of any rental or minimum royalty due under their leases. Rental or minimum royalty for lands of the United States subject to this agreement shall be paid at the rate specified in the respective leases from the United States unless such rental or minimum royalty is waived, suspended, or reduced by law or by approval of the Secretary or his duly authorized representative.

With respect to any lease on non-Federal land containing provisions which would terminate such lease unless drilling operations are commenced upon the land covered thereby within the time therein specified or rentals are paid for the privilege

of deferring such drilling operations, the rentals required thereby shall, notwithstanding any other provision of this agreement, be deemed to accrue and become payable during the term thereof as extended by this agreement and until the required drilling operations are commenced upon the land covered thereby, or until some portion of such land is included within a participating area.

16. CONSERVATION. Operations hereunder and production of unitized substances shall be conducted to provide for the most economical and efficient recovery of said substances without waste, as defined by or pursuant to State or Federal law or regulation.

17. DRAINAGE. (a) The Unit Operator shall take such measures as the AO deems appropriate and adequate to prevent drainage of unitized substances from unitized land by wells on land not subject to this agreement, which shall include the drilling of protective wells and which may include the payment of a fair and reasonable compensatory royalty, as determined by the AO.

(b) Whenever a participating area approved under section 11 of this agreement contains unleased Federal lands, the value of ____ *(current royalty for leases offered on Federal onshore oil and gas lease sales)* ____ percent of the production that would be allocated to such Federal lands under section 12 of this agreement, if such lands were leased, committed, and entitled to participation, shall be payable as compensatory royalties to the Federal Government. Parties to this agreement holding working interests in committed leases within the applicable participating area shall be responsible for such compensatory royalty payment on the volume of production reallocated from the unleased Federal lands to their unitized tracts under section 12. The value of such production subject to the payment of said royalties shall be determined pursuant to 30 CFR part 206. Payment of compensatory royalties on the production reallocated from unleased Federal land to the committed tracts within the participating area shall fulfill the Federal royalty obligation for such production, and said production shall be subject to no further royalty assessment under section 14 of this agreement. Payment of compensatory royalties as provided herein shall accrue from the date the committed tracts in the participating area that includes unleased Federal lands receive a production allocation, and shall be due and payable monthly by the last day of the calendar month next following the calendar month of actual production. If leased Federal lands receiving a production allocation from the participating area become unleased, compensatory royalties shall accrue from the date the Federal lands become unleased. Payment due under this provision shall end when the unleased Federal tract is leased or when production of unitized substances ceases within the participating area and the participating area is terminated, whichever occurs first.

18. LEASES AND CONTRACTS CONFORMED AND EXTENDED. The terms, conditions, and provisions of all leases, subleases, and other contracts relating to exploration, drilling, development or operation for oil or gas on lands committed to this agreement are hereby expressly modified and amended to the extent necessary to make the same conform to the provisions hereof, but otherwise to remain in full force and effect; and the parties hereto hereby consent that the Secretary shall and by his approval hereof, or by the approval hereof by his duly authorized representative, does hereby establish, alter, change, or revoke the drilling, producing, rental, minimum royalty, and royalty requirements of Federal leases committed hereto and the regulations in respect thereto to conform said requirements to the provisions of this agreement, and, without limiting the generality of the foregoing, all leases, subleases, and contracts are particularly modified in accordance with the following:

(a) The development and operation of lands subject to this agreement under the terms hereof shall be deemed full performance of all obligations for development and operation with respect to each and every separately owned tract subject to this agreement, regardless of whether there is any development of any particular tract of this unit area.

(b) Drilling and producing operations performed hereunder upon any tract of unitized lands will be accepted and deemed to be performed upon and for the benefit of each and every tract of unitized land, and no lease shall be deemed to expire by reason of failure to drill or produce wells situated on the land therein embraced.

(c) Suspension of drilling or producing operations on all unitized lands pursuant to direction or consent of the AO shall be deemed to constitute such suspension pursuant to such direction or consent as to each and every tract of unitized land. A suspension of drilling or producing operations limited to specified lands shall be applicable only to such lands.

(d) Each lease, sublease, or contract relating to the exploration, drilling, development, or operation for oil or gas of lands other than those of the United States committed to this agreement which, by its terms might expire prior to the termination of this agreement, is hereby extended beyond any such term so provided therein so that it shall be continued in full force and effect for and during the term of this agreement.

(e) Any Federal lease committed hereto shall continue in force beyond the term so provided therein or by law as to the land committed so long as such lease remains subject hereto, provided that production of unitized substances in paying quantities is established under this unit agreement prior to the expiration date of the term of such lease, or in the event actual drilling operations are commenced on unitized land, in accordance with provisions of this agreement, prior to the end of the primary term of such lease and are being diligently prosecuted at that time, such lease shall be extended for 2 years, and so long thereafter as oil or gas is produced in paying quantities in accordance with the provisions of the Mineral Leasing Act, as amended.

(f) Each sublease or contract relating to the operation and development of unitized substances from lands of the United States committed to this agreement, which by its terms would expire prior to the time at which the underlying lease, as extended by the immediately preceding paragraph, will expire is hereby extended beyond any such term so provided therein so that it shall be continued in full force and effect for and during the term of the underlying lease as such term is herein extended.

(g) The segregation of any Federal lease committed to this agreement is governed by the following provision in the fourth paragraph of sec. 17(m) of the Mineral Leasing Act, as amended by the Act of September 2, 1960 (74 Stat. 781–784) (30 U.S.C. 226(m)):

''Any [Federal] lease heretofore or hereafter committed to any such [unit] plan embracing lands that are in part within and in part outside of the area covered by any such plan shall be segregated into separate leases as to the lands committed and the lands not committed as of the effective date of unitization: *Provided, however,* That any such lease as to the nonunitized portion shall continue in force and effect for the term thereof but for not less than 2 years from the date of such segregation and so long thereafter as oil or gas is produced in paying quantities.''

If the public interest requirement is not satisfied, the segregation of a lease and/or extension of a lease pursuant to 43 CFR 3107.32 and 43 CFR 3107.40, respectively, shall not be effective.

[3] (h) Any lease, other than a Federal lease, having only a portion of its lands committed hereto shall be segregated as to the portion committed and the portion not committed, and the provisions of such lease shall apply separately to such segregated portions commencing as of the effective date hereof. In the event any such lease provides for a lump-sum rental payment, such payment shall be prorated between the portions so segregated in proportion to the acreage of the respective tracts.

19. COVENANTS RUN WITH LAND. The covenants herein shall be construed to be covenants running with the land with respect to the interests of the parties hereto and their successors in interest until this agreement terminates, and any grant, transfer or conveyance of interest in land or leases subject hereto shall be and hereby is conditioned upon the assumption of all privileges and obligations hereunder by the grantee, transferee, or other successor in interest. No assignment or transfer of any working interest, royalty, or other interest subject hereto shall be binding upon Unit Operator until the first day of the calendar month after Unit Operator is furnished with the original, photostatic, or certified copy of the instrument of transfer.

20. EFFECTIVE DATE AND TERM. This agreement shall become effective upon approval by the AO and shall automatically terminate 5 years from said effective date unless:

(a) Upon application by the Unit Operator such date of expiration is extended by the AO, or

(b) It is reasonably determined prior to the expiration of the fixed term or any extension

thereof that the unitized land is incapable of production of unitized substances in paying quantities in the formations tested hereunder, and after notice of intention to terminate this agreement on such ground is given by the Unit Operator to all parties in interest at their last known addresses, this agreement is terminated with the approval of the AO, or

(c) A valuable discovery of unitized substances in paying quantities has been made or accepted on unitized land during said initial term or any extension thereof, in which event this agreement shall remain in effect for such term and so long thereafter as unitized substances can be produced in quantities sufficient to pay for the cost of producing same from wells on unitized land within any participating area established hereunder. Should production cease and diligent drilling or reworking operations to restore production or new production are not in progress within 60 days and production is not restored or should new production not be obtained in paying quantities on committed lands within this unit area, this agreement will automatically terminate effective the last day of the month in which the last unitized production occurred, or

(d) It is voluntarily terminated as provided in this agreement. Except as noted herein, this agreement may be terminated at any time prior to the discovery of unitized substances which can be produced in paying quantities by not less than 75 per centum, on an acreage basis, of the working interest owners signatory hereto, with the approval of the AO. The Unit Operator shall give notice of any such approval to all parties hereto. If the public interest requirement is not satisfied, the approval of this unit by the AO shall be invalid.

21. RATE OF PROSPECTING, DEVELOPMENT, AND PRODUCTION. The AO is hereby vested with authority to alter or modify from time to time, in his discretion, the quantity and rate of production under this agreement when such quantity and rate are not fixed pursuant to Federal or State law, or do not conform to any Statewide voluntary conservation or allocation program which is established, recognized, and generally adhered to by the majority of operators in such State. The above authority is hereby limited to alteration or modifications which are in the public interest. The public interest to be served and the purpose thereof, must be stated in the order of alteration or modification. Without regard to the foregoing, the AO is also hereby vested with authority to alter or modify from time to time, in his discretion, the rate of prospecting and development and the quantity and rate of production under this agreement when such alteration or modification is in the interest of attaining the conservation objectives stated in this agreement and is not in violation of any applicable Federal or State law.

Powers is the section vested in the AO shall only be exercised after notice to Unit Operator and opportunity for hearing to be held not less than 15 days from notice.

22. APPEARANCES. The Unit Operator shall, after notice to other parties affected, have the right to appear for and on behalf of any and all interests affected hereby before the Department of the Interior and to appeal from orders issued under the regulations of said Department, or to apply for relief from any of said regulations, or in any proceedings relative to operations before the Department, or any other legally constituted authority; provided, however, that any other interested party shall also have the right at its own expense to be heard in any such proceeding.

23. NOTICES. All notices, demands, or statements required hereunder to be given or rendered to the parties hereto shall be in writing and shall be personally delivered to the party or parties, or sent by postpaid registered or certified mail, to the last-known address of the party or parties.

24. NO WAIVER OF CERTAIN RIGHTS. Nothing contained in this agreement shall be construed as a waiver by any party hereto of the right to assert any legal or constitutional right or defense as to the validity or invalidity of any law of the State where the unitized lands are located, or of the United States, or regulations issued thereunder in any way affecting such party, or as a waiver by any such party of any right beyond his or its authority to waive.

25. UNAVOIDABLE DELAY. All obligations under this agreement requiring the Unit Operator to commence or continue drilling, or to operate on, or produce unitized substances from any of the lands covered by this agreement, shall be suspended while the Unit Operator, despite the exercise of due care and diligence, is prevented from complying with such obligations, in whole or in part, by strikes, acts of God, Federal, State, or municipal law or agencies, unavoidable accidents, uncontrollable delays in transportation, inability to obtain necessary materials or equipment in the open market, or other matters beyond the reasonable control of the Unit Operator, whether similar to matters herein enumerated or not.

26. NONDISCRIMINATION. In connection with the performance of work under this agreement, the Unit Operator agrees to comply with all the provisions of section 202 (1) to (7) inclusive, of E.O. 11246 (30 FR 12319), as amended, which are hereby incorporated by reference in this agreement.

27. LOSS OF TITLE. In the event title to any tract of unitized land shall fail and the true owner cannot be induced to join in this unit agreement, such tract shall be automatically regarded as not committed hereto, and there shall be such readjustment of future costs and benefits as may be required on account of the loss of such title. In the event of a dispute as to title to any royalty, working interest, or other interests subject thereto, payment or delivery on account thereof may be withheld without liability for interest until the dispute is finally settled; provided, that, as to Federal lands or leases, no payments of funds due the United States shall be withheld, but such funds shall be deposited as directed by the AO, to be held as unearned money pending final settlement of the title dispute, and then applied as earned or returned in accordance with such final settlement.

Unit Operator as such is relieved from any responsibility for any defect or failure of any title hereunder.

28. NONJOINDER AND SUBSEQUENT JOINDER. If the owner of any substantial interest in a tract within the unit area fails or refuses to subscribe or consent to this agreement, the owner of the working interest in that tract may withdraw the tract from this agreement by written notice delivered to the proper BLM office and the Unit Operator prior to the approval of this agreement by the AO. Any oil or gas interests in lands within the unit area not committed hereto prior to final approval may thereafter be committed hereto by the owner or owners thereof subscribing or consenting to this agreement, and, if the interest is a working interest, by the owner of such interest also subscribing to the unit operating agreement. After operations are commenced hereunder, the right of subsequent joinder, as provided in this section, by a working interest owner is subject to such requirements or approval(s), if any, pertaining to such joinder, as may be provided for in the unit operating agreement. After final approval hereof, joinder by a nonworking interest owner must be consented to in writing by the working interest owner committed hereto and responsible for the payment of any benefits that may accrue hereunder in behalf of such nonworking interest. A nonworking interest may not be committed to this unit agreement unless the corresponding working interest is committed hereto. Joinder to the unit agreement by a working interest owner, at any time, must be accompanied by appropriate joinder to the unit operating agreement, in order for the interest to be regarded as committed to this agreement. Except as may otherwise herein be provided, subsequent joinders to this agreement shall be effective as of the date of the filing with the AO of duly executed counterparts of all or any papers necessary to establish effective commitment of any interest and/or tract to this agreement.

29. COUNTERPARTS. This agreement may be executed in any number of counterparts, no one of which needs to be executed by all parties, or may be ratified or consented to by separate instrument in writing specifically referring hereto and shall be binding upon all those parties who have executed such a counterpart, ratification, or consent hereto with the same force and effect as if all such parties had signed the same document, and regardless of whether or not it is executed by all other parties owning or claiming an interest in the lands within the above-described unit area.

[4] 30. SURRENDER. Nothing in this agreement shall prohibit the exercise by any working interest owner of the right to surrender vested in such party by any lease, sublease, or operating agreement as to all or any part of the lands covered thereby, provided that each party who will or might acquire such working interest by such surrender or by forfeiture as hereafter set forth, is bound by the terms of this agreement.

If as a result of any such surrender, the working interest rights as to such lands become vested in any party other than the fee owner of the unitized substances, said party may forfeit such rights and further benefits from operations hereunder as to said land to

the party next in the chain of title who shall be and become the owner of such working interest.

If as the result of any such surrender or forfeiture working interest rights become vested in the fee owner of the unitized substances, such owner may:

(a) Accept those working interest rights subject to this agreement and the unit operating agreement; or

(b) Lease the portion of such land as is included in a participating area established hereunder subject to this agreement and the unit operating agreement; or

(c) Provide for the independent operation of any part of such land that is not then included within a participating area established hereunder.

If the fee owner of the unitized substances does not accept the working interest rights subject to this agreement and the unit operating agreement or lease such lands as above provided within 6 months after the surrendered or forfeited, working interest rights become vested in the fee owner; the benefits and obligations of operations accruing to such lands under this agreement and the unit operating agreement shall be shared by the remaining owners of unitized working interests in accordance with their respective working interest ownerships, and such owners of working interests shall compensate the fee owner of unitized substances in such lands by paying sums equal to the rentals, minimum royalties, and royalties applicable to such lands under the lease in effect when the lands were unitized.

An appropriate accounting and settlement shall be made for all benefits accruing to or payments and expenditures made or incurred on behalf of such surrendered or forfeited working interests subsequent to the date of surrender or forfeiture, and payment of any moneys found to be owing by such an accounting shall be made as between the parties within 30 days.

The exercise of any right vested in a working interest owner to reassign such working interest to the party from whom obtained shall be subject to the same conditions as set forth in this section in regard to the exercise of a right to surrender.

[4] 31. TAXES. The working interest owners shall render and pay for their account and the account of the royalty owners all valid taxes on or measured by the unitized substances in and under or that may be produced, gathered and sold from the land covered by this agreement after its effective date, or upon the proceeds derived therefrom. The working interest owners on each tract shall and may charge the proper proportion of said taxes to royalty owners having interests in said-tract, and may currently retain and deduct a sufficient amount of the unitized substances or derivative products, or net proceeds thereof, from the allocated share of each royalty owner to secure reimbursement for the taxes so paid. No such taxes shall be charged to the United States or the State of _____ or to any lessor who has a contract with his lessee which requires the lessee to pay such taxes.

[4] 32. NO PARTNERSHIP. It is expressly agreed that the relation of the parties hereto is that of independent contractors and nothing contained in this agreement, expressed or implied, nor any operations conducted hereunder, shall create or be deemed to have created a partnership or association between the parties hereto or any of them.

In witness whereof, the parties hereto have caused this agreement to be executed and have set opposite their respective names the date of execution.

Unit Operator _____

Working Interest Owners _____

Other Interest Owners _____

General Guidelines

1. Executed agreement to be legally complete.

2. Agreement submitted for approval must contain Exhibit A and B in accordance with models shown in Appendix B to part 3180 and Appendix C to part 3180.

3. Consents should be identified (in pencil) by tract numbers as listed in Exhibit B and assembled in that order as far as practical. Unit agreements submitted for approval shall include a list of the overriding royalty interest owners who have executed ratifications of the unit agreement. Subsequent joinders by overriding royalty interest owners shall be submitted in the same manner, except each must include or be accompanied by a statement that the corresponding working interest owner has consented in writing to such joinder. Original ratifications of overriding royalty owners will be kept on file by the Unit Operator or his designated agent.

4. All leases held by option should be noted on Exhibit B with an explanation as to the type of option, *i.e.,* whether for operating rights only, for full leasehold record title, or for certain interests to be earned by performance. In all instances, optionee committing such interests is expected to exercise option promptly.

5. All owners of oil and gas interests must be invited to join the unit agreement, and statement to that effect must accompany executed agreement, together with summary of results of such invitations. A written reason for all interest owners who have not joined shall be furnished by the unit operator.

6. In the event fish and wildlife lands are included, add the following as a separate section:

''Wildlife Stipulation. Nothing in this unit agreement shall modify the special Federal lease stipulations applicable to lands under the jurisdiction of the United States Fish and Wildlife Service.''

7. In the event National Forest System lands are included within the unit area, add the following as a separate section:

''Forest Land Stipulation. Notwithstanding any other terms and conditions contained in this agreement, all of the stipulations and conditions of the individual leases between the United States and its lessees or their successors or assigns embracing lands within the unit area included for the protection of lands or functions under the jurisdiction of the Secretary of Agriculture shall remain in full force and effect the same as though this agreement had not been entered into, and no modification thereof is authorized except with the prior consent in writing of the Regional Forester, United States Forest Service, ____, _____.''

8. In the event National Forest System lands within the Jackson Hole Area of Wyoming are included within the unit area, additional ''special'' stipulations may be required to be included in the unit agreement by the U.S. Forest Service, including the Jackson Hole Special Stipulation.

9. In the event reclamation lands are included, add the following as a new separate section:

''Reclamation Lands. Nothing in this agreement shall modify the special, Federal lease stipulations applicable to lands under the jurisdiction of the Bureau of Reclamation.''

10. In the event a powersite is embraced in the proposed unit area, the following section should be added:

''Powersite. Nothing in this agreement shall modify the special, Federal lease stipulations applicable to lands under the jurisdiction of the Federal Energy Regulatory Commission.''

11. In the event special surface stipulations have been attached to any of the Federal oil and gas leases to be included, add the following as a separate section:

''Special surface stipulations. Nothing in this agreement shall modify the special Federal lease stipulations attached to the individual Federal oil leases.''

12. In the event State lands are included in the proposed unit area, add the appropriate State Lands Section as separate section. (See § 3181.4(a)).

13. In the event restricted Indian lands are involved, consult the AO regarding appropriate requirements under § 3181.4(b).

Certification—Determination

Pursuant to the authority vested in the Secretary of the Interior, under the Act approved February 25, 1920, 41 Stat. 437, as amended, 30 U.S.C. 181, *et seq.,* and delegated to (the appropriate Name and Title of the authorized officer, BLM) under the authority of 43 CFR part 3180, I do hereby:

A. Approve the attached agreement for the development and operation of the ____, Unit Area, State of _____. This approval shall be invalid *ab initio* if the public interest requirement under § 3183.4(b) is not met.

B. Certify and determine that the unit plan of development and operation contemplated in the attached agreement is necessary and advisable in the public interest for the purpose of more properly conserving the natural resources.

C. Certify and determine that the drilling, producing, rental, minimum royalty, and royalty requirements of all Federal leases committed to said agreement are hereby established altered, changed, or revoked to conform with the terms and conditions of this agreement.

Dated _____.

(Name and Title of authorized officer of the Bureau of Land Management)

Notes

[1] Optional sections (in addition the penultimate paragraph of Section 9 is to be included only when more than one

obligation well is required and paragraph (h) of section 18 is to be used only when applicable).

[2] Provisions to be included only when a multiple well obligation is required.

[3] Optional paragraph to be used only when applicable.

[4] Optional sections and subsection. (Agreements submitted for final approval should not identify section or provision as ''optional.'')

§ 3186.1–1 [Redesignated as Appendix B to Part 3180]

■ 25. Redesignate § 3186.1–1 as appendix B to part 3180.

§ 3186.1–2 [Redesignated as Appendix C to Part 3180]

■ 26. Redesignate § 3186.1–2 as appendix C to part 3180.

§ 3186.2 [Removed]

■ 27. Remove § 3186.2.

§ 3186.3 [Redesignated as Appendix D to part 3180]

■ 28. Redesignate § 3186.3 as appendix D to part 3180.

§ 3186.4 [Redesignated as Appendix E to part 3180]

■ 29. Redesignate § 3186.4 as appendix E to part 3180.

This action by the Principal Deputy Assistant Secretary is taken pursuant to an existing delegation of authority.

Steven H. Feldgus,

Principal Deputy Assistant Secretary, Land and Minerals Management.

[FR Doc. 2024–08138 Filed 4–22–24; 8:45 am]

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Part V

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Phase 2 Construction of the Vineyard Wind 1 Offshore Wind Project Off Massachusetts; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD687]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Phase 2 Construction of the Vineyard Wind 1 Offshore Wind Project Off Massachusetts

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization.

SUMMARY: NMFS has received a request from Vineyard Wind LLC (Vineyard Wind) for authorization to take marine mammals incidental to the completion of the construction of a commercial wind energy project offshore Massachusetts in the northern portion of Lease Area OCS–A 0501. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities; which consists of a subset of activities for which take was authorized previously, but which Vineyard Wind did not complete within the effective dates of the previous IHA. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision. The IHA would be valid for 1 year from date of issuance.

DATES: Comments and information must be received no later than May 23, 2024.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources (OPR), NMFS and should be submitted via email to *ITP.taylor@noaa.gov.* Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jessica Taylor, OPR, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment. NMFS participated as a cooperating agency on the Bureau of Ocean Energy Management (BOEM) 2021 Environmental Impact Statement (EIS) for the Vineyard Wind 1 Offshore Wind Project.

NMFS' proposal to issue Vineyard Wind the requested IHA constitutes a federal action subject to NEPA (42 U.S.C. 4321 *et seq.*). On May 10, 2021, NMFS adopted the Bureau of Ocean Energy Management's (BOEM) Vineyard Wind 1Final Environmental Impact Statement (FEIS), published on March 12, 2021 and available at: *https://www.boem.gov/renewable-energy/state-activities/vineyard-wind-1.* NMFS is currently evaluating if supplementation of the Vineyard Wind 1 EIS is required per 40 CFR 1502.9(d). We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On December 15, 2023, NMFS received a request from Vineyard Wind for an IHA to take marine mammals incidental to Phase 2 construction of the Vineyard Wind Offshore Wind Project off Massachusetts, specifically wind turbine generator (WTG) monopile foundation installation, in the northern portion of Lease Area OCS–A 0501. Vineyard Wind completed installation of 47 WTG monopiles and 1 electrical service platform (ESP) jacket foundation in 2023 under an IHA issued by NMFS on June 25, 2021 (86 FR 33810) with effective dates from May 1, 2023, through April 30, 2024. Due to unexpected delays, Vineyard Wind was not able to complete pile driving activities before the expiration date of the current IHA (April 30, 2024); thus, Vineyard Wind is requesting take of marine mammals incidental to installing the remaining 15 monopiles to complete foundation installation for the Project. In total, the Project will consist of 62 WTG monopiles and 1 offshore substation.

Following NMFS' review of the December 2023 application, Vineyard Wind submitted multiple revised versions of the application, and it was deemed adequate and complete on March 13, 2024. Vineyard Wind's request is for take of 14 species of marine mammals, by Level B harassment and, for 6 of these species, Level A harassment. Neither Vineyard

Wind nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Vineyard Wind previously conducted high resolution geophysical (HRG) site characterization surveys within the Lease Area and associated export cable corridor in 2016, 2018–2021, and June–December 2023 (ESS Group *Inc.,* 2016; Vineyard Wind 2018, 2019; EPI Group, 2021; RPS, 2022; Vineyard Wind 2023a–f). During the 2023 construction season, NMFS coordinated closely with Vineyard Wind to ensure compliance with their IHA. In a few instances, NMFS raised concerns with Vineyard Wind regarding their implementation of certain required measures. NMFS worked closely with Vineyard Wind throughout the construction season to course correct, where needed, and ensure compliance with the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHA, and information regarding their monitoring results may be found in the Estimated Take of Marine Mammals section.

Description of Proposed Activity

Overview

Vineyard Wind proposes to construct and operate an 800-megawatt (MW) wind energy facility, the Project, in the Atlantic Ocean in Lease area OCS–A 0501, offshore of Massachusetts. The project would consist of up to 62 offshore wind turbine generators (WTGs), 1 electrical service platform (ESP), an onshore substation, offshore and onshore cabling, and onshore operations and maintenance facilities. The onshore substation and ESP are now complete. Installation of 47 monopile foundations was completed under a current IHA (86 FR 33810, June 25, 2021), effective from May 1, 2023, through April 30, 2024. However, due to unexpected, Vineyard Wind will not be able to complete pile driving activities before the expiration date of the current IHA (April 30, 2024). Take of marine mammals, in the form of behavioral harassment and limited instances of auditory injury, may occur incidental to the installation of the remaining 15 WTG monopile foundations due to in-water noise exposure resulting from impact pile driving. The remaining 15 monopile foundations would occur within a Limited Installation Area (LIA) (64.3 square kilometers (km^2; 15,888.9 acres)) within the Lease Area (264.4 km^2 (65,322.4 acres)). Installation of the remaining 15 monopile foundations is expected to occur in 2024.

Dates and Duration

The proposed pile driving activities are planned to occur in 2024 after the IHA is issued and, while not planned, may occur in June or July in 2025. Pile driving activities are estimated to require approximately 15 nonconsecutive days (30 nonconsecutive hours of pile driving). Given vessel availability, weather delay, and logistical constraints, these 15 days for installation of the remaining monopile foundations could occur close in time or spread out over months.

Although installation of a single monopile may last for several hours, active pile driving for installation of a single monopile is expected to last for a maximum of 2 hours. Up to 1 monopile may be installed per day, based upon the average pile driving time (up to 2 hours) for the installation of the currently installed 47 monopiles. Monopile foundations would be installed in batches of three to six monopiles at a time as this represents the maximum batch size that the installation vessel can carry to the LIA. After installation of a batch of three to six monopiles, there would be a 4 to 7 day pause in monopile installation to allow time for the installation vessel to return with a new batch of monopiles. No concurrent monopile installation is proposed. Vineyard Wind has proposed, and NMFS would require, that pile driving activities be prohibited from January 1 through May 31 due to the increased presence of North Atlantic right whales (NARWs) in the LIA and the timing of the project (*i.e.,* pile driving in May is not practicable). NMFS is also proposing to restrict pile driving in December to the maximum extent practicable.

Specific Geographic Region

Vineyard Wind's would construct the Project in within Federal waters off Massachusetts, in the northern portion of the Vineyard Wind Lease Area OCS–A 0501 (figure 1). This area is also referred to as the Wind Development Area (WDA). The 15 remaining monopiles would be installed in a LIA within a portion of the southwest corner of the WDA. The LIA is approximately 70.5 km^2 (17,420.9 acres) in size, as compared to the overall size of the Lease Area (264.4 km^2 (63,322.4 acres)). At its nearest point, the LIA is approximately 29 kilometers (km; 18.1 miles (mi)) from the southeast corner of Martha's Vineyard and a similar distance from Nantucket. Water depths in the WDA range from approximately 37 to 49.5 meters (m; 121–162 feet (ft)). Water depth and bottom habitat are similar throughout the Lease Area (Pyc *et al.,* 2018).

Vineyard Wind's specified activities would occur in the Northeast U.S. Continental Shelf Large Marine Ecosystem (NES LME), an area of approximately 260,000 km^2 from Cape Hatteras in the south to the Gulf of Maine in the north. Specifically, the LIA is located within the Mid-Atlantic Bight subarea of the NES LME, which extends between Cape Hatteras, North Carolina, and Martha's Vineyard, Massachusetts, extending westward into the Atlantic to the 100-m isobath. The specific geographic region includes the LIA as well as the crew transfer vessel transit corridors (see Proposed Mitigation section) and cable laying routes. The installation vessel and support vessels would conduct approximately three trips to Canada during the period of the IHA, transiting from New Bedford and nearby ports. Figure 1 shows the LIA and planned locations for the remaining 15 monopiles to be installed.

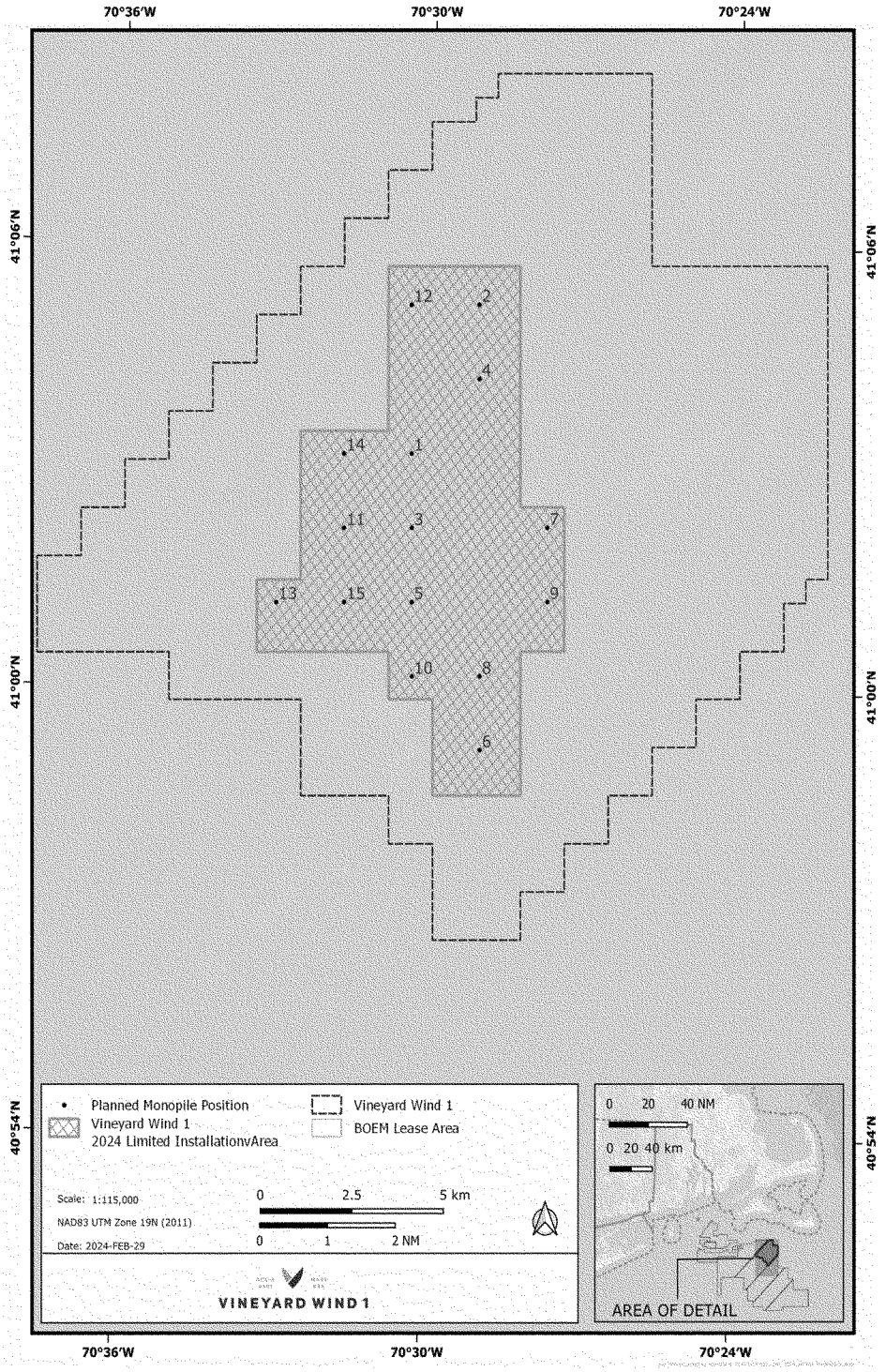

Figure 1 -- Vineyard Wind Limited Installation Area

Detailed Description of the Specified Activity

Monopile Installation

Vineyard Wind proposes to install 15 monopile WTG foundations in the LIA (figure 1) to complete the Vineyard Wind Offshore Wind Project (84 FR 18346, April 30, 2019; 86 FR 33810, June 25, 2021). Vineyard Wind assumes all monopile foundations would be installed using an impact hammer. Individual monopile installation would be sequenced according to the numbers in the cross-hatched area in figure 1.

A WTG monopile foundation typically consists of a coated single steel tubular section, with several sections of rolled steel plate welded together. Each 13–MW monopile would have a maximum diameter of 9.6 m (31.5 ft). WTGs would be arranged in a grid-like pattern within the LIA with spacing of

1.9 km (1 nautical mile (nmi)) between turbines, and driven to a maximum penetration depth of 28 m (92 ft) to 35 m (115 ft) below the seafloor (Vineyard Wind, 2023). Monopile foundations would consist of a monopile with a separate transition piece.

Monopile foundations would be installed by a heavy lift vessel. The installation vessel would upend the monopile with a crane and place it in a gripper frame before lowering the monopile foundation to the seabed (see figure 4 in IHA application). Vineyard Wind would use a Monopile Installation Tool (MPIT) to seat the monopile foundation and protect against pile gripper damage as well as risks to human safety associated with pile run. The MPIT creates buoyancy within the monopile foundation using air pressure to control lowering the monopile through the pile run risk zone (Vineyard Wind, 2023). As the monopile foundation is lowered, air is released from the top of the foundation above the water surface until the pile is stabilized within the seabed. Once the monopile is lowered to the seabed, the crane hook would be released. A hydraulic impact hammer would be placed on top of the monopile and used to drive the monopile into the seabed to the target penetration depth (28–35 m). Monopile foundations would be installed using a maximum hammer energy of 4,000 kilojoules (kJ) (table 1). Pile driving would begin with a 20-minute soft-start at reduced hammer energy (see Proposed Mitigation). The hammer energy would gradually be increased based upon resistance experienced from sediments. Prior to pile driving, the MPIT process may last from 6 to 15 hours and is dependent upon local soil conditions at each monopile foundation (Vineyard Wind, 2023). Vineyard Wind anticipates that one monopile would be installed per day at a rate of approximately 2 hours of active pile driving time per monopile (table 1). Rock scour protection would be applied after foundation installation. The scour protection would be 1–2 m high (3–6 ft), with stone or rock sizes of approximately 10–30 centimeters (4–12 inches).

While post-piling activities could be ongoing at one foundation position as pile driving is occurring at another position, no concurrent/simultaneous pile driving of foundations would occur (see *Dates and Duration* section). Installation of monopile foundations is anticipated to result in the take of marine mammals due to noise generated during pile driving. Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

TABLE 1—IMPACT PILE DRIVING SCHEDULE

Pile type	Project component	Max hammer energy (kJ)	Number of hammer strikes	Max piling time duration per pile (min)	Max piling time duration per day (min)	Number piles/day
9.6-m monopile	WTG	[a] 4000	[b] 2,884	117	117	1

[a] Maximum hammer energy for representative monopiles installed during the 2023 Vineyard Wind Offshore Wind Project construction ranged from 3,227 to 3,831 kJ.

[b] Number of hammer strikes based upon the AU–38 representative monopile installed during the 2023 Vineyard Wind Offshore Wind Project construction period at a maximum hammer energy of 3,825 kJ.

After monopile installation, transition pieces, containing work platforms and other ancillary structures, and WTGs, consisting of a tower and the energy-generating components of the turbine, would be installed. Transition pieces and WTGs would be installed on top of monopile foundations using jack-up vessels. However, installation of transition pieces and WTGS on monopile foundations is not expected to result in take of marine mammals and, therefore, are not discussed further.

Vineyard Wind has developed a sequencing plan for installation of monopiles throughout the LIA, as shown in figure 1. The sequencing plan will allow for several of the monopiles located in the northeast corner of the LIA and highest density area of NARWs, to be installed first.

Vineyard Wind anticipates that it is possible for the 15 WTGs to become operational within the effective period of the IHA. Nine of the 47 WTGs previously installed in 2023 are currently operational.

Vessel Operation

Vineyard Wind would use various types of vessels over the course of the 1-year proposed IHA for foundation installation and transporting monopile batches between ports and the LIA (table 2). Construction-related vessel activity is anticipated to include approximately 20 vessels operating throughout the specified geographic area on any given work day. Many of these vessels would remain in the LIA for days or weeks at a time, making infrequent trips to port for bunkering and provisioning, as needed. Table 2 shows the type and number of vessels Vineyard Wind would use for various construction activities as well as the associated ports. Vineyard Wind would utilize ports in New London, Connecticut and New Bedford, Massachusetts (table 2) to support offshore construction, crew transfer and logistics, and other operational activities. In addition, monopile foundations would come from a Canadian port in Halifax. Monopile foundations would be transported on an installation vessel to the LIA from Canada, and would be installed in batches of three to six monopiles at a time. Upon completion of installation of a batch of monopiles, the installation vessel would return to Canada to load an additional batch of monopiles (Vineyard Wind, 2023). For the proposed activities, it is expected that the installation vessel would need to make a maximum of three trips between Canada and the LIA.

As part of vessel-based construction activities, dynamic positioning thrusters would be utilized to hold vessels in position or move slowly during monopile installation. Sound produced through use of dynamic positioning thrusters is similar to that produced by transiting vessels, and dynamic positioning thrusters are typically operated either in a similarly predictable manner or used for short durations around stationary activities. Construction-related vessel activity, including the use of dynamic positioning thrusters, is not expected to result in take of marine mammals. While a vessel strike could cause injury or mortality of a marine mammal, Vineyard Wind proposed and NMFS is proposing to require, extensive vessel strike avoidance measures that would avoid vessel strikes from occurring (see Proposed Mitigation and Proposed Monitoring and Reporting). Vineyard Wind did not request, and NMFS

neither anticipates nor proposes to authorize, take associated with vessel activity, and this activity is not analyzed further.

TABLE 2—TYPE AND NUMBER OF VESSELS ANTICIPATED DURING CONSTRUCTION

Vessel type	Vessel role	Maximum number of vessels	Expected maximum number of transits per month	Port
Heavy lift vessel	Pile driving	1	2	Halifax, Canada.
Trans-shipment vessel	Bubble curtain	2	4	New London, CT.
Fishing vessel	PSO support vessel	2	3	New Bedford, MA.
	Service operations vessel	1	4	
	Safety vessel	4	2	
Motor vessel	Crew transfer vessel	2	12	

Inter-Array Cable Laying

Inter-array cables would be installed to connect WTGs to the ESP. In 2023, Vineyard Wind completed approximately 40 percent of the installation of inter-array cables in the Lease Area. Vineyard Wind anticipates approximately 50 percent of the inter-array cable laying to take place during the effective period of the IHA. Vineyard Wind would perform a pre-lay grapnel run to remove any obstructions, such as fishing gear, from the seafloor. The cable would be laid on the seafloor and buried using a jet trencher with scour added for cable protection near the transition pieces and ESPs. The sounds associated with cable laying are consistent with those of routine vessel operations and not expected to result in take of marine mammals. Inter-array cable laying activities are, therefore, not discussed further.

Other Activities

Vineyard Wind would not conduct high-resolution geophysical (HRG) surveys, UXO/MEC detonation, or fishery research surveys under this IHA.

Description of Marine Mammals in the Area of Specified Activities

Thirty-eight marine mammal species, comprising 39 stocks, under NMFS' jurisdiction have geographic ranges within the western North Atlantic OCS (Hayes *et al.,* 2023). However, for reasons described below, Vineyard Wind has requested, and NMFS proposes to authorize, take of only 14 species (comprising 14 stocks) of marine mammals. Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. See **ADDRESSES**. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 3 lists all species or stocks for which take is expected and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs; 16 U.S.C. 1362(20)). While no serious injury or mortality is anticipated or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats. Four of the marine mammal species for which take is requested are listed as endangered under the ESA, including the NARW, fin whale, sei whale, and sperm whale.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprise that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. 2023 draft SARs and NMFS' U.S. 2022 SARs. For the majority of species potentially present in the specific geographic region, NMFS has designated only a single generic stock (*e.g.,* ''western North Atlantic'') for management purposes. This includes the ''Canadian east coast'' stock of minke whales, which includes all minke whales found in United States waters and is also a generic stock for management purposes. For humpback and sei whales, NMFS defines stocks on the basis of feeding locations (*i.e.,* Gulf of Maine and Nova Scotia, respectively). However, references to humpback whales and sei whales in this document refer to any individuals of the species that are found in the specific geographic region. All values presented in table 3 are the most recent available at the time of publication and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 3—MARINE MAMMAL SPECIES THAT MAY OCCUR IN THE LIA AND BE TAKEN BY HARASSMENT

Common name [a]	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [b]	Stock abundance (CV, N_{min}, most recent abundance survey) [c]	PBR	Annual M/SI [d]
Order Artiodactyla—Cetacea—Mysticeti (baleen whales)						
Family Balaenidae:						
NARW	*Eubalaena glacialis*	Western Atlantic	E, D, Y	340 (0; 337; 2021) [e]	0.7	27.2 [f]
Family Balaenopteridae (rorquals):						
Fin whale	*Balaenoptera physalus*	Western North Atlantic	E, D, Y	6,802 (0.24, 5,573, 2021)	11	2.05
Sei whale	*Balaenoptera borealis*	Nova Scotia	E, D, Y	6,292 (1.02, 3098, 2021)	6.2	0.6
Minke whale	*Balaenoptera acutorostrata.*	Canadian Eastern Coastal	-, -, N	21,968 (0.31, 17,002, 2021).	170	9.4
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	-, -, Y	1,396 (0, 1,380, 2016)	22	12.15
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Physeteridae:						
Sperm whale	*Physeter macrocephalus*	North Atlantic	E, D, Y	5,895 (0.29, 4,639, 2021)	9.28	0.2
Family Delphinidae:						
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic	-, -, N	39,215 (0.3, 30,627, 2021).	306	5.7
Bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Offshore	-, -, N	64,587 (0.24, 52,801, 2021) [g].	507	28
Common dolphin	*Delphinus delphis*	Western North Atlantic	-, -, N	93,100 (0.56, 59,897, 2021).	1,452	414
Risso's dolphin	*Grampus griseus*	Western North Atlantic	-, -, N	44,067 (0.19, 30,662, 2021).	307	18
Atlantic white-sided dolphin	*Lagenorhynchus acutus*	Western North Atlantic	-, -, N	93,233 (0.71, 54,443, 2021).	544	28
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	Gulf of Maine/Bay of Fundy	-, -, N	85,765 (0.53, 56,420, 2021).	649	145
Order Carnivora—Pinnipedia						
Family Phocidae (earless seals):						
Harbor seal	*Phoca vitulina*	Western North Atlantic	-, -, N	61,336 (0.08, 57,637, 2018).	1,729	339
Gray seal [h]	*Halichoerus grypus*	Western North Atlantic	-, -, N	27,911 (0.2, 23,924, 2021).	1,512	4,570

[a] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies;* Committee on Taxonomy, 2023).

[b] ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR, or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[c] NMFS 2022 marine mammal SARs online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is the coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[d] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, ship strike).

[e] The draft 2023 SAR includes an estimated population (N_{best} 340) based on sighting history through December 2021 (89 FR 5495, January 29, 2024). In October 2023, NMFS released a technical report identifying that the NARW population size based on sighting history through 2022 was 356 whales, with a 95 percent credible interval ranging from 346 to 363 (Linden, 2023).

[f] Total annual average observed NARW mortality during the period 2017–2021 was 7.1 animals and annual average observed fishery mortality was 4.6 animals. Numbers presented in this table (27.2 total mortality and 17.6 fishery mortality) are 2016–2020 estimated annual means, accounting for undetected mortality and serious injury.

[g] As noted in the draft 2023 SAR (89 FR 5495, January 29, 2024), abundance estimates may include sightings of the coastal form.

[h] NMFS' stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 394,311. The annual M/SI value given is for the total stock.

As indicated above, all 14 species (with 14 managed stocks) in table 3 temporally and spatially co-occur with the activity to the degree that take is expected to occur. The following species are not expected to occur in the LIA due to their known distributions, preferred habitats, and/or known temporal and spatial occurrences: the blue whale (*Balaenoptera musculus*), northern bottlenose whale (*Hyperoodon ampullatus*), false killer whale (*Pseudorca crassidens*), pygmy killer whale (*Feresa attenuata*), melon-headed whale (*Peponocephala electra*), dwarf and pygmy sperm whales (*Kogia* spp.), killer whale (*Orcinus orca*), Cuvier's beaked whale (*Ziphius cavirostris*), four species of Mesoplodont whale (*Mesoplodon densitostris, M. europaeus, M. mirus,* and *M. bidens*), Fraser's dolphin (*Lagenodelphis hosei*), Clymene dolphin (*Stenella clymene*), spinner dolphin (*Stenella longirostris*), rough-toothed dolphin (*Steno bredanensis*), Atlantic spotted dolphin (*Stenella frontalis*), pantropical spotted dolphin (*Stenella attenuata*), short-finned pilot whale (*Globicephala macrorhynchus*), striped dolphin (*Stenella coeruleoalba*), white-beaked dolphin (*Lagenorhynchus albirostris*), and hooded seal (*Crysophora cristata*). None of these species were observed during the 2023 construction season or during previous site assessment/characterization surveys (Vineyard Wind, 2018, 2019, 2023a–f). Due to the lack of sightings of these species in the MA Wind Energy Area (WEA) (Kenney and Vigness-Raposa, 2010; ESS Group, *Inc.,* 2016; Kraus *et al.,* 2016; Vineyard Wind, 2018; 2019; O'Brien *et al.,* 2020, 2021, 2022, 2023; EPI Group, 2021; Palka *et al.,* 2017 2021; RPS, 2022; Vineyard Wind, 2023a–f; Hayes *et al.,* 2023) as well as documented habitat preferences and distributions, we have determined that

each of these species will not be considered further. Furthermore, the northern limit of the northern migratory coastal stock of the common bottlenose dolphin (*Tursiops truncatus*) does not extend as far north as the LIA. Thus, take is only proposed for the offshore stock which may occur within the LIA. Although harp seals (*Pagophilus groenlandicus*) are expected to occur within the WDA, no harp seals were observed by Protected Species Observers (PSOs) during Vineyard Wind's site characterization surveys (2016, 2018–2021; ESS Group, *Inc.,* 2016; Vineyard Wind, 2018, 2019) nor during the 2023 construction campaign (Vineyard Wind, 2023a-f). Thus, Vineyard Wind did not request, and NMFS is not proposing to authorize, take for this species.

In addition to what is included in sections 3 and 4 of Vineyard Wind's ITA application (Vineyard Wind, 2023), the SARs (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*), and NMFS' website (*https://www.fisheries.noaa.gov/species-directory/marine-mammals*), we provide further detail below informing the baseline for select species (*e.g.,* information regarding current unusual mortality events (UMEs) and known important habitat areas, such as biologically important areas (BIAs; *https://oceannoise.noaa.gov/biologically-important-areas*) (Van Parijs, 2015)). There are no ESA-designated critical habitats for any species within the LIA (*https://www.fisheries.noaa.gov/resource/map/national-esa-critical-habitat-mapper*). Any areas of known biological importance (including the BIAs identified in LaBrecque *et al.,* 2015) that overlap spatially (or are adjacent) with the LIA are addressed in the species sections below.

Under the MMPA, a UME is defined as ''a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response'' (16 U.S.C. 1421h(6)). As of January 2024, three UMEs are occurring along the U.S. Atlantic coast for NARWs, humpback whales, and minke whales. Of these, the most relevant to the LIA are the NARW and humpback whale UMEs given the prevalence of these species in Southern New England (SNE). Below, we include information for a subset of the species that presently have an active or recently closed UME occurring along the Atlantic coast or for which there is information available related to areas of biological significance. More information on UMEs, including all active, closed, or pending, can be found on NMFS' website at *https://www.fisheries.noaa.gov/national/marine-life-distress/active-and-closed-unusual-mortality-events.*

North Atlantic Right Whale

The NARW has been listed as Endangered since the ESA's enactment in 1973. The species was recently uplisted from Endangered to Critically Endangered on the International Union for Conservation of Nature Red List of Threatened Species (Cooke, 2020). The uplisting was due to a decrease in population size (Pace *et al.,* 2017), an increase in vessel strikes and entanglements in fixed fishing gear (Daoust *et al.,* 2017; Davis & Brillant, 2019; Knowlton *et al.,* 2012; Knowlton *et al.,* 2022; Moore *et al.,* 2021; Sharp *et al.,* 2019), and a decrease in birth rate (Pettis *et al.,* 2022; Reed *et al.,* 2022). The western Atlantic stock is considered depleted under the MMPA (Hayes *et al.,* 2023). There is a recovery plan (NMFS, 2005) for the NARW, and NMFS completed 5-year reviews of the species in 2012, 2017, and 2022, which concluded no change to the listing status is warranted.

The NARW population had only a 2.8-percent recovery rate between 1990 and 2011 and an overall abundance decline of 23.5 percent from 2011 to 2019 (Hayes *et al.,* 2023). Since 2011, the NARW population has been in decline; however, the sharp decrease observed from 2015 to 2020 appears to have slowed, though the right whale population continues to experience annual mortalities above recovery thresholds (Pace *et al.,* 2017; Pace *et al.,* 2021; Linden, 2023). NARW calving rates dropped from 2017 to 2020 with zero births recorded during the 2017–2018 season. The 2020–2021 calving season had the first substantial calving increase in 5 years with 20 calves born (including 2 mortalities) followed by 15 calves during the 2021–2022 calving season and 12 births (including 1 mortality) in 2022–2023 calving season. These data demonstrate that birth rates are increasing. However, mortalities continue to outpace births (Linden, 2023). Best estimates indicate fewer than 70 reproductively active females remain in the population and adult females experience a lower average survival rate than males (Linden, 2023). In 2023, the total annual average observed NARW mortality increased from 8.1 (which represents 2016–2020) to 31.2 (which represents 2015–2019), however, this updated estimate also accounts for undetected mortality and serious injury (Hayes *et al.,* 2023). Although the predicted number of deaths from the population are lower in recent years (2021–2022) when compared to the high number of deaths from 2014 to 2020, suggesting a short-term increase in survival, annual mortality rates still exceed PBR (Linden, 2023).

NMFS' regulations at 50 CFR 224.105 designated Seasonal Management Areas (SMAs) for NARWs in 2008 (73 FR 60173, October 10, 2008). SMAs were developed to reduce the threat of collisions between vessels and NARWs. A portion of the Block Island SMA, which occurs off Block Island, Rhode Island, is near the LIA (approximately 4.3 km (2.7 mi) southwest of the OCS–A 0501 Lease Area at the closest point), but does not overlap spatially with the Lease Area or LIA. This SMA is active from November 1 through April 30 of each year, and may be used by NARWs for migrating and/or feeding. As noted below, NMFS is proposing changes to the NARW speed rule (87 FR 46921, August 1, 2022). NMFS has designated critical habitat for NARWs (81 FR 4838, January 27, 2016), along the U.S. southeast coast for calving as well as in the northeast, just east of the LIA. The LIA both spatially and temporally overlaps a portion of a migratory corridor BIA (LaBrecque *et al.,* 2015). Due to the current status of NARWs and the spatial proximity of the proposed project with areas of biological significance, (*i.e.,* a migratory corridor, SMA), the potential impacts of the proposed project on NARWs warrant particular attention.

NARWs range from calving grounds in the southeastern United States to feeding grounds in New England waters and into Canadian waters (Hayes *et al.,* 2023). Surveys have demonstrated the existence of seven areas where NARWs congregate seasonally in Georges Bank, off Cape Cod, and in Massachusetts Bay (Hayes *et al.,* 2023). In late fall (*i.e.,* November), a portion of the NARW population (including pregnant females) typically departs the feeding grounds in the North Atlantic, moves south along the migratory corridor BIA, including through the LIA, to calving grounds off Georgia and Florida. This movement is followed by a northward migration (primarily mothers with young calves) into northern feeding areas in March and April (LaBrecque *et al.,* 2015; Van Parijs, 2015). Recent research indicates our understanding of their movement patterns remains incomplete and not all of the population undergoes a consistent annual migration (Davis *et al.,* 2017; Gowan *et al.,* 2019; Krzystan *et al.,* 2018). Non-calving females may remain in the feeding grounds during the winter in the years preceding and following the

birth of a calf to increase their energy stores (Gowen *et al.,* 2019). NARWs may migrate through the LIA to access more northern feeding grounds or southern calving grounds.

NARWs may occur year-round in SNE, near Martha's Vineyard and Nantucket Shoals as well as throughout the Massachusetts and Rhode Island/Massachusetts Wind Energy Areas (MA and RI/MA WEAs) (Quintan-Rizzo *et al.,* 2021; O'Brien *et al.,* 2023; Van Parijs *et al.,* 2023). Kraus *et al.* (2016) found acoustic detections in SNE to peak during the winter and early spring (January through March). Visual surveys (Quintana-Rizzo *et al.,* 2021) have also confirmed the abundance of NARWs in SNE to be the highest during the winter and spring (January through May), although peaks in acoustic detections may vary seasonally across years (Quintana-Rizzo *et al.,* 2021; Estabrook *et al.,* 2022). Distribution throughout SNE may vary seasonally with NARW occurrence being closest to the LIA during the spring (Quintana-Rizzo *et al.,* 2021). Van Parijs *et al.* (2023) monitored acoustic detections of baleen whales throughout SNE and detected NARWs near the LIA from January through May. Acoustic detections began to increase near the LIA in November and further increased into December (Van Parijs *et al.,* 2023).

An 8-year analysis of NARW sightings within SNE showed that the NARW distribution has been shifting (Quintana-Rizzo *et al.,* 2021). NARWs feed primarily on the copepod, *Calanus finmarchicus,* a species whose availability and distribution has changed both spatially and temporally over the last decade due to an oceanographic regime shift that has been ultimately linked to climate change (Meyer-Gutbrod *et al.,* 2021; Record *et al.,* 2019; Sorochan *et al.,* 2019). This distribution change in prey availability has led to shifts in NARW habitat-use patterns over the same time period (Davis *et al.,* 2020; Meyer-Gutbrod *et al.,* 2022; Quintano-Rizzo *et al.,* 2021; O'Brien *et al.,* 2022; Pendleton *et al.,* 2022; Van Parijs *et al.,* 2023), with reduced use of foraging habitats in the Great South Channel and Bay of Fundy and increased use of habitats within Cape Cod Bay and a region south of Martha's Vineyard and Nantucket Islands (Stone *et al.,* 2017; Mayo *et al.,* 2018; Ganley *et al.,* 2019; Record *et al.,* 2019; Meyer-Gutbrod *et al.,* 2021; Van Parijs *et al.,* 2023). Pendleton *et al.* (2022) observed shifts in the timing of NARW peak habitat use in Cape Cod Bay during the spring, likely in response to changing seasonal conditions, and characterized SNE as a ''waiting room'' for NARWs in the spring, providing sufficient, although sub-optimal, prey choices while the NARWs wait for foraging conditions in Cape Cod Bay (and other primary foraging grounds such as the Great South Channel) to optimize as seasonal primary and secondary production progresses.

While Nantucket Shoals is not designated as critical NARW habitat, its importance as a foraging habitat is well established (Leiter *et al.,* 2017; Quintana-Rizzo *et al.,* 2021; Estabrook *et al.,* 2022; O'Brien *et al.,* 2022). Nantucket Shoals' unique oceanographic and bathymetric features, including a persistent tidal front, help sustain year-round elevated phytoplankton biomass, and aggregate zooplankton prey for NARWs (Quintana-Rizzo *et al.,* 2021). SNE serves as a foraging habitat throughout the year, although not to the extent provided seasonally in more well-understood feeding habitats like Cape Cod Bay in late spring, the Great South Channel, and the Gulf of St. Lawrence (O'Brien *et al.,* 2022). A BIA for foraging (LaBrecque *et al.,* 2015) within Cape Cod Bay is approximately 71 km (44.1 mi) north of the LIA, while critical habitat northeast of Martha's Vineyard and Nantucket Island is within 56 km (34.8 mi). SNE also represents socializing habitat for NARWs as Leiter *et al.* (2017) documented surface active groups (SAGs), indicative of socializing behavior, year-round in SNE.

Observations of NARW transitions in habitat use, variability in seasonal presence in identified core habitats, and utilization of habitat outside of previously focused survey effort prompted the formation of a NMFS' Expert Working Group, which identified current data collection efforts, data gaps, and provided recommendations for future survey and research efforts (Oleson *et al.,* 2020). In addition, extensive data gaps that were highlighted in a recent report by the National Academy of Sciences (NAS, 2023) have prevented development of a thorough understanding of NARW foraging ecology in the Nantucket Shoals region. However, it is clear that the habitat was historically valuable to the species, given that the whaling industry capitalized on consistent NARW occurrence there, and has again become increasingly so over the last decade.

Since 2017, 125 dead, seriously injured, or sublethally injured or ill NARWs along the United States and Canadian coasts have been documented, necessitating a UME declaration in 2017 and subsequent investigation. The leading category for the cause of death for this ongoing UME is ''human interaction,'' specifically from entanglements or vessel strikes. As of April 9, 2024, there have been 39 confirmed mortalities, 1 pending mortality (dead, stranded, or floaters), and 34 seriously injured free-swimming whales for a total of 73 whales. Beginning on October 14, 2022, the UME also considers animals with sublethal injury or illness bringing the total number of whales in the UME to 125. Approximately 42 percent of the population is known to be in reduced health (Hamilton *et al.,* 2021) likely contributing to smaller body sizes at maturation, making them more susceptible to threats and reducing fecundity (Moore *et al.,* 2021; Reed *et al.,* 2022; Stewart *et al.,* 2022; Pirotta *et al.,* 2024). Pirotta *et al.* (2024) found an association between the decreased mean length of female NARWs and reduced calving probability. More information about the NARW UME is available online at *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2024-north-atlantic-right-whale-unusual-mortality-event.*

On August 1, 2022, NMFS announced proposed changes to the existing NARW vessel speed regulations to further reduce the likelihood of mortalities and serious injuries to endangered right whales from vessel collisions, which are a leading cause of the species' decline and a primary factor in the ongoing Unusual Mortality Event (87 FR 46921, August 1, 2022). Should a final vessel speed rule be issued and become effective during the effective period of this IHA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. These changes would become effective immediately upon the effective date of any final vessel speed rule and would not require any further action on NMFS's part.

Humpback Whale

Humpback whales were listed as endangered under the Endangered Species Conservation Act (ESCA) in June 1970. In 1973, the ESA replaced the ESCA, and humpbacks continued to

be listed as endangered. On September 8, 2016, NMFS divided the once single species into 14 distinct population segments (DPS), removed the species-level listing, and, in its place, listed four DPSs as endangered and one DPS as threatened (81 FR 62259, September 8, 2016). The remaining nine DPSs were not listed. The West Indies DPS, which is not listed under the ESA, is the only DPS of humpback whales that is expected to occur in the LIA. Bettridge *et al.* (2015) estimated the size of the West Indies DPS population at 12,312 (95 percent confidence interval 8,688–15,954) whales in 2004–2005, which is consistent with previous population estimates of approximately 10,000–11,000 whales (Stevick *et al.,* 2003; Smith *et al.,* 1999) and the increasing trend for the West Indies DPS (Bettridge *et al.,* 2015).

In New England waters, feeding is the principal activity of humpback whales, and their distribution in this region has been largely correlated to abundance of prey species, although behavior and bathymetry are factors influencing foraging strategy (Payne *et al.,* 1986, 1990). Humpback whales are frequently piscivorous when in New England waters, feeding on herring (*Clupea harengus*), sand lance (*Ammodytes* spp.), and other small fishes, as well as euphausiids in the northern Gulf of Maine (Paquet *et al.,* 1997). During winter, the majority of humpback whales from North Atlantic feeding areas (including the Gulf of Maine) mate and calve in the West Indies, where spatial and genetic mixing among feeding groups occurs, though significant numbers of animals are found in mid- and high-latitude regions at this time and some individuals have been sighted repeatedly within the same winter season, indicating that not all humpback whales migrate south every winter (Hayes *et al.,* 2018).

Kraus *et al.* (2016) conducted aerial surveys from 2011–2015 in SNE and observed humpback whales during all seasons, yet humpback whales were observed most often during the spring and summer. The greatest number of sightings occurred during the month of April (*n*=33) (Kraus *et al.,* 2016). Calves, feeding behavior, and courtship behavior were observed as well. More recent studies (O'Brien *et al.,* 2020, 2021, 2022, 2023) confirm that humpback whales peak in abundance in the LIA during spring and summer, with the majority of sightings year-round occurring in the eastern portion of the MA and RI/MA WEAs and near the Nantucket Shoals area (O'Brien *et al.,* 2020). O'Brien *et al.* (2022) identified seasonal distribution patterns of humpback whales throughout SNE with more concentrated sightings near Nantucket Shoals in the fall and sightings being distributed more evenly across the MA and RI/MA WEAs during spring and summer. As observed during the 2011–2015 surveys, O'Brien *et al.* (2023) also observed feeding behavior and mother/calf pairs throughout the spring and summer. Van Parijs *et al.* (2023) detected humpback whales near the LIA mainly from November through June. During the Vineyard Wind 2023 construction campaign, visual and acoustic detections of humpback whales occurred mainly from June through October, with the greatest detections occuring in October (Vineyard Wind, 2023).

The LIA does not overlap with any BIAs or other important areas for the humpback whales. A humpback whale feeding BIA extends throughout the Gulf of Maine, Stellwagen Bank, and Great South Channel from May through December, annually (LaBrecque *et al.,* 2015). This BIA is located approximately 73 km (45.5 mi) northeast of the Lease Area and would not likely be impacted by project activities.

Since January 2016, elevated humpback whale mortalities along the Atlantic coast from Maine to Florida led to the declaration of a UME in April 2017. As of April 9, 2024, 218 humpback whales have stranded as part of this UME. Partial or full necropsy examinations have been conducted on approximately 90 of the known cases. Of the whales examined, about 40 percent had evidence of human interaction, either ship strike or entanglement. While a portion of the whales have shown evidence of pre-mortem vessel strike, this finding is not consistent across all whales examined and more research is needed. Since January 1, 2023, 43 humpbacks have stranded along the east coast of the United States (7 of these whales have stranded off Massachusetts). These whales may have been following their prey (small fish) which were reportedly close to shore this past winter. These prey also attract fish that are targeted by recreational and commercial fishermen, which increases the number of boats in these areas. More information is available at *https://www.fisheries.noaa.gov/national/marine-life-distress/active-and-closed-unusual-mortality-events.*

Fin Whale

Fin whales frequently occur in the waters of the U.S. Atlantic Exclusive Economic Zone (EEZ), principally from Cape Hatteras, North Carolina northward and are distributed in both continental shelf and deep-water habitats (Hayes *et al.,* 2023). Although fin whales are present north of the 35-degree latitude north region in every season and are broadly distributed throughout the western North Atlantic for most of the year, densities vary seasonally (Edwards *et al.,* 2015; Hayes *et al.,* 2023). Fin whales typically feed in the Gulf of Maine and the waters surrounding New England, but their mating and calving (and general wintering) areas are largely unknown (Hain *et al.,* 1992; Hayes *et al.,* 2023). Acoustic detections of fin whale singers augment and confirm these visual sighting conclusions for males. Recordings from Massachusetts Bay, New York Bight, and deep-ocean areas have detected some level of fin whale singing from September through June (Watkins *et al.,* 1987; Clark and Gagnon, 2002; Morano *et al.,* 2012). These acoustic observations from both coastal and deep-ocean regions support the conclusion that male fin whales are broadly distributed throughout the western North Atlantic for most of the year (Hayes *et al.,* 2022).

New England waters represent a major feeding ground for fin whales, and fin whale feeding BIAs occur offshore of Montauk Point, New York, from March to October (2,933 km^2) (Hain *et al.,* 1992; LaBrecque *et al.,* 2015) and year-round in the southern Gulf of Maine (18,015 km^2). Aerial surveys conducted from 2011–2015 in SNE documented fin whale occurrence in every season, with the greatest numbers of sightings during the spring (*n*=35) and summer (*n*=49) months (Kraus *et al.,* 2016). Fin whale distribution varied seasonally, with fin whales occurring in the southern regions of the MA and RI/MA WEAs during spring and closer to northern regions of the WEAs during summer (Kraus *et al.,* 2016). More recent surveys have documented fin whales throughout winter, spring, and summer (O'Brien *et al.,* 2020, 2021, 2022, 2023) with the greatest abundance occurring during the summer and clustered in the western portion of the WEAs (O'Brien *et al.,* 2023). Acoustic detection of fin whales in SNE indicate fin whale presence in the area from August through April and, sporadically, from May through July (Parijs *et al.,* 2023). During the 2023 construction campaign, Vineyard Wind detected fin whales from June through December (with the exception of August), with the most detections occurring in October (Vineyard Wind, 2023). Based upon observations of feeding behavior and the close proximity of the Lease Area to the

feeding BIAs (8.0 km (5.0 mi) and 76.4 km (47.5 mi) to the Montauk Point and southern Gulf of Maine BIAs, respectively) fin whales may use the LIA for foraging as well as migrating.

Minke Whale

Minke whales are common and widely distributed throughout the U.S. Atlantic EEZ (Cetacean and Turtle Assessment Program (CETAP), 1982; Hayes *et al.,* 2022), although their distribution has a strong seasonal component. Individuals have often been detected acoustically in shelf waters from spring to fall and more often detected in deeper offshore waters from winter to spring (Risch *et al.,* 2013). Minke whales are abundant in New England waters from May through September (Pittman *et al.,* 2006; Waring *et al.,* 2014), yet largely absent from these areas during the winter, suggesting the possible existence of a migratory corridor (LaBrecque *et al.,* 2015). A migratory route for minke whales transiting between northern feeding grounds and southern breeding areas may exist to the east of the LIA, as minke whales may track warmer waters along the continental shelf while migrating (Risch *et al.,* 2014). Risch *et al.* (2014) suggests the presence of a minke whale breeding ground offshore of the southeastern US during the winter.

There are two minke whale feeding BIAs identified in the southern and southwestern section of the Gulf of Maine, including Georges Bank, the Great South Channel, Cape Cod Bay and Massachusetts Bay, Stellwagen Bank, Cape Anne, and Jeffreys Ledge from March through November, annually (LaBrecque *et al.,* 2015). The nearest BIA is approximately 44.0 km (27.3 mi) northeast of the Lease Area. Due to the close proximity of the BIA, minke whale feeding may occur within the LIA.

Although minke whales are sighted in every season in SNE (O'Brien *et al.,* 2022), minke whale use of the area is highest during the months of March through September (Kraus *et al.,* 2016; O'Brien *et al.,* 2023). Large feeding aggregations of humpback, fin, and minke whales have been observed during the summer (O'Brien *et al.,* 2023), suggesting the LIA may serve as a supplemental feeding grounds for these species. Acoustic detections data support visual sighting data, and indicate minke whale presence in SNE from March through June and August through late November/early December and, sporadically, in January (Parijs *et al.,* 2023). During the 2023 construction campaign, Vineyard Wind detected minke whales from June through August (Vineyard Wind, 2023).

From 2017 through 2024, elevated minke whale mortalities detected along the Atlantic coast from Maine through South Carolina resulted in the declaration of a UME in 2018. As of April 9, 2024, a total of 166 minke whale mortalities have occurred during this UME. Full or partial necropsy examinations were conducted on more than 60 percent of the whales. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease, but these findings are not consistent across all of the minke whales examined, so more research is needed. More information is available at *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2022-minke-whale-unusual-mortality-event-along-atlantic-coast.*

Sei Whale

The Nova Scotia stock of sei whales can be found in deeper waters of the continental shelf edge of the eastern United States and northeastward to south of Newfoundland (Mitchell, 1975; Hain *et al.,* 1985; Hayes *et al.,* 2022). During spring and summer, the stock is mainly concentrated in northern feeding areas, including the Scotian Shelf (Mitchell and Chapman, 1977), the Gulf of Maine, Georges Bank, the Northeast Channel, and south of Nantucket (CETAP, 1982; Kraus *et al.,* 2016; Roberts *et al.,* 2016; Palka *et al.,* 2017; Cholewiak *et al.,* 2018; Hayes *et al.,* 2022). Sei whales have been detected acoustically along the Atlantic Continental Shelf and Slope from south of Cape Hatteras, North Carolina to the Davis Strait, with acoustic occurrence increasing in the mid-Atlantic region since 2010 (Davis *et al.,* 2020). Sei whale migratory movements are not well understood. In June and July, sei whales are believed to migrate north from SNE to feeding areas in eastern Canada, and south in September and October to breeding areas (Mitchell, 1975; CETAP, 1982; Davis *et al.,* 2020). Sei whales generally occur offshore; however, individuals may also move into shallower, more inshore waters (Payne *et al.,* 1990; Halpin *et al.,* 2009; Hayes *et al.,* 2022). A sei whale feeding BIA occurs in New England waters from May through November, approximately 101.4 km (63 mi) east of the LIA (LaBrecque *et al.,* 2015).

Aerial surveys conducted from 2011–2015 in SNE observed sei whales between March and June, with the greatest number of sightings occurring in May (n=8) and June (n=13), and no sightings from July through January (Kraus *et al.,* 2016). Acoustic detections confirm peak occurrences of sei whales in SNE from early spring and through mid-summer (March through July) (Davis *et al.,* 2020). In addition, Van Parijs *et al.* (2023) acoustically detected sei whales near the LIA during the months of February and August. However, Davis *et al.* (2020) acoustically detected sei whales in SNE year-round, suggesting this area is an important habitat for sei whales. As sei whales are known to target the prey such as copepods (*C. finmarchicus*), which are abundant in SNE waters (Quintana-Rizzo *et al.,* 2018), SNE likely represents a supplemental foraging area for sei whales as well.

Phocid Seals

Harbor and gray seals have experienced multiple UMEs since 2018. From June through July 2022, elevated numbers of harbor seal and gray seal mortalities occurred across the southern and central coast of Maine. This event was declared a UME. During the event, 181 seals stranded. Based upon necropsy, histopathology, and diagnostic findings, this UME was attributed to spillover events of the highly pathogenic avian influenza from infected birds to harbor and gray seals. While the UME did not occur in the LIA, the populations that were affected by the UME are the same as those potentially affected by the project. This UME has recently been closed. Information on this UME is available online at *https://www.fisheries.noaa.gov/2022-2023-pinniped-unusual-mortality-event-along-maine-coast.*

The above event was preceded by a different UME, occurring from 2018 to 2020 (closure of the 2018–2020 UME is pending). Beginning in July 2018, elevated numbers of harbor seal and gray seal mortalities occurred across Maine, New Hampshire, and Massachusetts. Additionally, stranded seals have shown clinical signs as far south as Virginia, although not in elevated numbers, therefore the UME investigation encompassed all seal strandings from Maine to Virginia. A total of 3,152 reported strandings (of all species) occurred from July 1, 2018, through March 13, 2020. Full or partial necropsy examinations have been conducted on some of the seals and samples have been collected for testing. Based on tests conducted thus far, the main pathogen found in the seals is phocine distemper virus. NMFS is performing additional testing to identify any other factors that may be involved

in this UME, which is pending closure. Information on this UME is available online at: *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018-2020-pinniped-unusual-mortality-event-along.*

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, *Cephalorhynchid, Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on the ~65-dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.,* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth *et al.,* 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Vineyard Wind has requested, and NMFS proposes to authorize, the take of marine mammals incidental to the construction activities associated with the LIA. In their application, Vineyard Wind presented their analyses of potential impacts to marine mammals from the acoustic sources. NMFS carefully reviewed the information provided by Vineyard Wind, as well as independently reviewed applicable scientific research and literature and other information to evaluate the potential effects of the Project's activities on marine mammals.

The proposed activities would result in the construction and placement of 15 permanent foundations to support WTGs. There are a variety of types and degrees of effects to marine mammals, prey species, and habitat that could occur as a result of the Project. Below we provide a brief description of the types of sound sources that would be generated by the project, the general impacts from these types of activities, and an analysis of the anticipated impacts on marine mammals from the project, with consideration of the proposed mitigation measures.

Description of Sound Sources

This section contains a brief technical background on sound, on the characteristics of certain sound types, and on metrics used in this proposal inasmuch as the information is relevant to the specified activity and to a discussion of the potential effects of the specified activity on marine mammals found later in this document. For general information on sound and its interaction with the marine environment, please see: Au and Hastings, 2008; Richardson *et al.,* 1995; Urick, 1983; as well as the Discovery of Sound in the Sea (DOSITS) website at *https://www.dosits.org.* Sound is a vibration that travels as an acoustic wave through a medium such as a gas, liquid, or solid. Sound waves alternately compress and decompress the medium as the wave travels. These compressions and decompressions are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones (underwater microphones). In water, sound waves radiate in a manner similar to ripples on the surface of a pond and may be either directed in a beam (narrow beam or directional sources) or sound beams may radiate in all directions (omnidirectional sources).

Sound travels in water more efficiently than almost any other form of energy, making the use of acoustics ideal for the aquatic environment and its inhabitants. In seawater, sound

travels at roughly 1,500 meters per second (m/s). In-air, sound waves travel much more slowly, at about 340 m/s. However, the speed of sound can vary by a small amount based on characteristics of the transmission medium, such as water temperature and salinity. Sound travels in water more efficiently than almost any other form of energy, making the use of acoustics ideal for the aquatic environment and its inhabitants. In seawater, sound travels at roughly 1,500 m/s. In-air, sound waves travel much more slowly, at about 340 m/s. However, the speed of sound can vary by a small amount based on characteristics of the transmission medium, such as water temperature and salinity.

The basic components of a sound wave are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks or corresponding points of a sound wave (length of one cycle). Higher frequency sounds have shorter wavelengths than lower frequency sounds, and typically attenuate (decrease) more rapidly, except in certain cases in shallower water.

The intensity (or amplitude) of sounds is measured in dB, which is a relative unit of measurement that is used to express the ratio of one value of a power or field to another. Decibels are measured on a logarithmic scale, so a small change in dB corresponds to large changes in sound pressure. For example, a 10-dB increase is a ten-fold increase in acoustic power. A 20-dB increase is then a hundred-fold increase in power and a 30-dB increase is a thousand-fold increase in power. However, a ten-fold increase in acoustic power does not mean that the sound is perceived as being 10 times louder. Decibels are a relative unit comparing two pressures; therefore, a reference pressure must always be indicated. For underwater sound, this is 1 microPascal (µPa). For in-air sound, the reference pressure is 20 microPascal (µPa). The amplitude of a sound can be presented in various ways; however, NMFS typically considers three metrics. In this proposed IHA, all decibel levels are referenced to (re) 1µPa.

Sound exposure level (SEL) represents the total energy in a stated frequency band over a stated time interval or event and considers both amplitude and duration of exposure (represented as dB re 1 μPa^2 -s). SEL is a cumulative metric; it can be accumulated over a single pulse (for pile driving this is often referred to as single-strike SEL; SEL_{ss}) or calculated over periods containing multiple pulses (SEL_{cum}). Cumulative SEL represents the total energy accumulated by a receiver over a defined time window or during an event. The SEL metric is useful because it allows sound exposures of different durations to be related to one another in terms of total acoustic energy. The duration of a sound event and the number of pulses, however, should be specified as there is no accepted standard duration over which the summation of energy is measured.

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Root mean square is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Root mean square accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Peak sound pressure (also referred to as zero-to-peak sound pressure or 0-pk) is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source and is represented in the same units as the rms sound pressure. Along with SEL, this metric is used in evaluating the potential for permanent threshold shift (PTS) and temporary threshold shift (TTS).

Sounds can be either impulsive or non-impulsive. The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.,* Ward, 1997 in Southall *et al.,* 2007). Please see NMFS *et al.* (2018) and Southall *et al.* (2007, 2019a) for an in-depth discussion of these concepts. Impulsive sound sources (*e.g.,* airguns, explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than 1 second), broadband, atonal transients (American National Standards Institute (ANSI), 1986; ANSI, 2005; Harris, 1998; National Institute for Occupational Safety and Health (NIOSH), 1998; International Organization for Standardization (ISO), 2003) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features. Impulsive sounds are typically intermittent in nature.

Non-impulsive sounds can be tonal, narrowband, or broadband, brief, or prolonged, and may be either continuous or intermittent (ANSI, 1995; NIOSH, 1998). Some of these non-impulsive sounds can be transient signals of short duration but without the essential properties of pulses (*e.g.,* rapid rise time). Examples of non-impulsive sounds include those produced by vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems. Sounds are also characterized by their temporal component. Continuous sounds are those whose sound pressure level remains above that of the ambient sound with negligibly small fluctuations in level (NIOSH, 1998; ANSI, 2005) while intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). NMFS identifies Level B harassment thresholds based on if a sound is continuous or intermittent.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound, which is defined as environmental background sound levels lacking a single source or point (Richardson *et al.,* 1995). The sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.,* wind and waves, earthquakes, ice, atmospheric sound), biological (*e.g.,* sounds produced by marine mammals, fish, and invertebrates), and anthropogenic (*e.g.,* vessels, dredging, construction) sound. A number of sources contribute to ambient sound, including wind and waves, which are a main source of naturally occurring ambient sound for frequencies between 200 Hz and 50 kHz (International Council for the Exploration of the Sea (ICES), 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Precipitation can become an important component of total sound at frequencies above 500 Hz and possibly down to 100 Hz during quiet times. Marine mammals can contribute significantly to ambient sound levels as can some fish and snapping shrimp. The frequency band for biological contributions is from approximately 12 Hz to over 100 kHz. Sources of ambient sound related to

human activity include transportation (surface vessels), dredging and construction, oil and gas drilling and production, geophysical surveys, sonar, and explosions. Vessel noise typically dominates the total ambient sound for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz, and if higher frequency sound levels are created, they attenuate rapidly.

The sum of the various natural and anthropogenic sound sources that comprise ambient sound at any given location and time depends not only on the source levels (as determined by current weather conditions and levels of biological and human activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.,* 1995). The result is that, depending on the source type and its intensity, sound from a specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals. Human-generated sound is a significant contributor to the acoustic environment in the project location.

Potential Effects of Underwater Sound on Marine Mammals

Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life from none or minor to potentially severe responses depending on received levels, duration of exposure, behavioral context, and various other factors. Broadly, underwater sound from active acoustic sources, such as those in the Project, can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2003; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015).

In general, the degree of effect of an acoustic exposure is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure, in addition to the contextual factors of the receiver (*e.g.,* behavioral state at time of exposure, age class, *etc.*). In general, sudden, high-level sounds can cause hearing loss as can longer exposures to lower-level sounds. Moreover, any temporary or permanent loss of hearing will occur almost exclusively for noise within an animal's hearing range. We describe below the specific manifestations of acoustic effects that may occur based on the activities proposed by Vineyard Wind. Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur in relation to distance from a source and assuming that the signal is within an animal's hearing range. First (at the greatest distance) is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone (closer to the receiving animal) corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. The third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

Below, we provide additional detail regarding potential impacts on marine mammals and their habitat from noise in general, starting with hearing impairment, as well as from the specific activities Vineyard Wind plans to conduct, to the degree it is available (noting that there is limited information regarding the impacts of offshore wind construction on marine mammals).

Hearing Threshold Shift

Marine mammals exposed to high-intensity sound or to lower-intensity sound for prolonged periods can experience hearing threshold shift (TS), which NMFS defines as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level expressed in decibels (NMFS, 2018). Threshold shifts can be permanent, in which case there is an irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range or temporary, in which there is reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range and the animal's hearing threshold would fully recover over time (Southall *et al.,* 2019a). Repeated sound exposure that leads to TTS could cause PTS.

When PTS occurs, there can be physical damage to the sound receptors in the ear (*i.e.,* tissue damage) whereas TTS represents primarily tissue fatigue and is reversible (Henderson *et al.,* 2008). In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997; Southall *et al.,* 2019a). Therefore, NMFS does not consider TTS to constitute auditory injury.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS data for cetaceans. However, such relationships are assumed to be similar to those in humans and other terrestrial mammals. Noise exposure can result in either a permanent shift in hearing thresholds from baseline (a 40–dB threshold shift approximates a PTS onset; *e.g.,* Kryter *et al.,* 1966; Miller, 1974; Henderson *et al.,* 2008) or a temporary, recoverable shift in hearing that returns to baseline (a 6–dB threshold shift approximates a TTS onset; *e.g.,* Southall *et al.,* 2019a). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds, expressed in the unweighted peak sound pressure level metric (PK), for impulsive sounds (such as impact pile driving pulses) are at least 6 dB higher than the TTS thresholds and the weighted PTS cumulative sound exposure level thresholds are 15 (impulsive sound) to 20 (non-impulsive sounds) dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.,* 2019a). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, PTS is less likely to occur as a result of these activities; however, it is possible, and a small amount has been proposed for authorization for several species.

TTS is the mildest form of hearing impairment that can occur during

exposure to sound, with a TTS of 6 dB considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.,* 2000; Finneran *et al.,* 2000; Finneran *et al.,* 2002). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. There is data on sound levels and durations necessary to elicit mild TTS for marine mammals, but recovery is complicated to predict and dependent on multiple factors.

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious depending on the degree of interference of marine mammals hearing. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical (*e.g.,* for successful mother/calf interactions, consistent detection of prey) could have more serious impacts.

Currently, TTS data only exist for four species of cetaceans (bottlenose dolphin, beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocaena asiaeorientalis*)) and six species of pinnipeds (northern elephant seal (*Mirounga angustirostris*), harbor seal, ring seal, spotted seal, bearded seal, and California sea lion (*Zalophus californianus*)) that were exposed to a limited number of sound sources (*i.e.,* mostly tones and octave-band noise with limited number of exposure to impulsive sources such as seismic airguns or impact pile driving) in laboratory settings (Southall *et al.,* 2019a). There is currently no data available on noise-induced hearing loss for mysticetes. For summaries of data on TTS or PTS in marine mammals or for further discussion of TTS or PTS onset thresholds, please see Southall *et al.* (2019a) and NMFS (2018).

Recent studies with captive odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale) have observed increases in hearing threshold levels when individuals received a warning sound prior to exposure to a relatively loud sound (Nachtigall and Supin, 2013, 2015; Nachtigall *et al.,* 2016a–c, 2018; Finneran, 2018). These studies suggest that captive animals have a mechanism to reduce hearing sensitivity prior to impending loud sounds. Hearing change was observed to be frequency dependent and Finneran (2018) suggests hearing attenuation occurs within the cochlea or auditory nerve. Based on these observations on captive odontocetes, the authors suggest that wild animals may have a mechanism to self-mitigate the impacts of noise exposure by dampening their hearing during prolonged exposures of loud sound or if conditioned to anticipate intense sounds (Finneran, 2018; Nachtigall *et al.,* 2018).

Behavioral Effects

Exposure of marine mammals to sound sources can result in, but is not limited to, no response or any of the following observable responses: increased alertness; orientation or attraction to a sound source; vocal modifications; cessation of feeding; cessation of social interaction; alteration of movement or diving behavior; habitat abandonment (temporary or permanent); and in severe cases, panic, flight, stampede, or stranding, potentially resulting in death (Southall *et al.,* 2007). A review of marine mammal responses to anthropogenic sound was first conducted by Richardson (1995). More recent reviews address studies conducted since 1995 and focused on observations where the received sound level of the exposed marine mammal(s) was known or could be estimated (Nowacek *et al.,* 2007; DeRuiter *et al.,* 2013; Ellison *et al.,* 2012; Gomez *et al.,* 2016). Gomez *et al.* (2016) conducted a review of the literature considering the contextual information of exposure in addition to received level and found that higher received levels were not always associated with more severe behavioral responses and vice versa. Southall *et al.* (2021) states that results demonstrate that some individuals of different species display clear yet varied responses, some of which have negative implications while others appear to tolerate high levels and that responses may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, the authors state that differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability.

Behavioral responses to sound are highly variable and context-specific. Many different variables can influence an animal's perception of and response to (nature and magnitude) an acoustic event. An animal's prior experience with a sound or sound source affects whether it is less likely (habituation) or more likely (sensitization) to respond to certain sounds in the future (animals can also be innately predisposed to respond to certain sounds in certain ways) (Southall *et al.,* 2019a). Related to the sound itself, the perceived nearness of the sound, bearing of the sound (approaching vs. retreating), the similarity of a sound to biologically relevant sounds in the animal's environment (*i.e.,* calls of predators, prey, or conspecifics), and familiarity of the sound may affect the way an animal responds to the sound (Southall *et al.,* 2007; DeRuiter *et al.,* 2013). Individuals (of different age, gender, reproductive status, *etc.*) among most populations will have variable hearing capabilities, and differing behavioral sensitivities to sounds that will be affected by prior conditioning, experience, and current activities of those individuals. Often, specific acoustic features of the sound and contextual variables (*i.e.,* proximity, duration, or recurrence of the sound or the current behavior that the marine mammal is engaged in or its prior experience), as well as entirely separate factors, such as the physical presence of a nearby vessel, may be more relevant to the animal's response than the received level alone.

Overall, the variability of responses to acoustic stimuli depends on the species receiving the sound, the sound source, and the social, behavioral, or environmental contexts of exposure (*e.g.,* DeRuiter and Doukara, 2012). For example, Goldbogen *et al.* (2013a) demonstrated that individual behavioral state was critically important in determining response of blue whales to sonar, noting that some individuals engaged in deep (greater than 50 m) feeding behavior had greater dive responses than those in shallow feeding or non-feeding conditions. Some blue whales in the Goldbogen *et al.* (2013a) study that were engaged in shallow feeding behavior demonstrated no clear changes in diving or movement even when received levels were high (~160 dB re 1µPa (microPascal)) for exposures to 3–4 kHz sonar signals, while deep feeding and non-feeding whales showed a clear response at exposures at lower

received levels of sonar and pseudorandom noise. Southall *et al.* (2011) found that blue whales had a different response to sonar exposure depending on behavioral state, more pronounced when deep feeding/travel modes than when engaged in surface feeding.

With respect to distance influencing disturbance, DeRuiter *et al.* (2013) examined behavioral responses of Cuvier's beaked whales to mid-frequency sonar and found that whales responded strongly at low received levels (89–127 dB re 1µPa) by ceasing normal fluking and echolocation, swimming rapidly away, and extending both dive duration and subsequent non-foraging intervals when the sound source was 3.4–9.5 km (2.1–5.9 mi) away. Importantly, this study also showed that whales exposed to a similar range of received levels (78–106 dB re 1µPa) from distant sonar exercises (118 km, or 73.3 mi, away) did not elicit such responses, suggesting that context may moderate reactions. Thus, distance from the source is an important variable in influencing the type and degree of behavioral response and this variable is independent of the effect of received levels (*e.g.,* DeRuiter *et al.,* 2013; Dunlop *et al.,* 2017a–b, 2018; Falcone *et al.,* 2017; Southall *et al.,* 2019a).

Ellison *et al.* (2012) outlined an approach to assessing the effects of sound on marine mammals that incorporates contextual-based factors. The authors recommend considering not just the received level of sound, but also the activity the animal is engaged in at the time the sound is received, the nature and novelty of the sound (*i.e.,* is this a new sound from the animal's perspective), and the distance between the sound source and the animal. They submit that this ''exposure context,'' as described, greatly influences the type of behavioral response exhibited by the animal. Forney *et al.* (2017) also point out that an apparent lack of response (*e.g.,* no displacement or avoidance of a sound source) may not necessarily mean there is no cost to the individual or population, as some resources or habitats may be of such high value that animals may choose to stay, even when experiencing stress or hearing loss. Forney *et al.* (2017) recommend considering both the costs of remaining in an area of noise exposure such as TTS, PTS, or masking, which could lead to an increased risk of predation or other threats or a decreased capability to forage, and the costs of displacement, including potential increased risk of vessel strike, increased risks of predation or competition for resources, or decreased habitat suitable for foraging, resting, or socializing. This sort of contextual information is challenging to predict with accuracy for ongoing activities that occur over large spatial and temporal expanses. However, distance is one contextual factor for which data exist to quantitatively inform a take estimate, and the method for predicting Level B harassment in this IHA does consider distance to the source. Other factors are often considered qualitatively in the analysis of the likely consequences of sound exposure where supporting information is available.

Behavioral change, such as disturbance manifesting in lost foraging time, in response to anthropogenic activities is often assumed to indicate a biologically significant effect on a population of concern. However, individuals may be able to compensate for some types and degrees of shifts in behavior, preserving their health and thus their vital rates and population dynamics. For example, New *et al.* (2013) developed a model simulating the complex social, spatial, behavioral, and motivational interactions of coastal bottlenose dolphins in the Moray Firth, Scotland, to assess the biological significance of increased rate of behavioral disruptions caused by vessel traffic. Despite a modeled scenario in which vessel traffic increased from 70 to 470 vessels a year (a six-fold increase in vessel traffic) in response to the construction of a proposed offshore renewables facility, the dolphins' behavioral time budget, spatial distribution, motivations, and social structure remained unchanged. Similarly, two bottlenose dolphin populations in Australia were also modeled over 5 years against a number of disturbances (Reed *et al.,* 2020) and results indicate that habitat/noise disturbance had little overall impact on population abundances in either location, even in the most extreme impact scenarios modeled. Friedlaender *et al.* (2016) provided the first integration of direct measures of prey distribution and density variables incorporated into across-individual analyses of behavior responses of blue whales to sonar and demonstrated a five-fold increase in the ability to quantify variability in blue whale diving behavior. These results illustrate that responses evaluated without such measurements for foraging animals may be misleading, which again illustrates the context-dependent nature of the probability of response.

The following subsections provide examples of behavioral responses that give an idea of the variability in behavioral responses that would be expected given the differential sensitivities of marine mammal species to sound, contextual factors, and the wide range of potential acoustic sources to which a marine mammal may be exposed. Behavioral responses that could occur for a given sound exposure should be determined from the literature that is available for each species, or extrapolated from closely related species when no information exists, along with contextual factors.

Avoidance and Displacement

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.,* 1995). For example, gray whales (*Eschrichtius robustus*) and humpback whales are known to change direction—deflecting from customary migratory paths—in order to avoid noise from airgun surveys (Malme *et al.,* 1984; Dunlop *et al.,* 2018). Avoidance is qualitatively different from the flight response but also differs in the magnitude of the response (*i.e.,* directed movement, rate of travel, *etc.*). Avoidance may be short-term with animals returning to the area once the noise has ceased (*e.g.,* Malme *et al.,* 1984; Bowles *et al.,* 1994; Goold, 1996; Stone *et al.,* 2000; Morton and Symonds, 2002; Gailey *et al.,* 2007; Dähne *et al.,* 2013; Russel *et al.,* 2016). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006; Forney *et al.,* 2017). Avoidance of marine mammals during the construction of offshore wind facilities (specifically, impact pile driving) has been documented in the literature with some significant variation in the temporal and spatial degree of avoidance and with most studies focused on harbor porpoises as one of the most common marine mammals in European waters (*e.g.,* Tougaard *et al.,* 2009; Dähne *et al.,* 2013; Thompson *et al.,* 2013; Russell *et al.,* 2016; Brandt *et al.,* 2018).

Available information on impacts to marine mammals from pile driving associated with offshore wind is limited to information on harbor porpoises and seals, as the vast majority of this research has occurred at European offshore wind projects where large whales and other odontocete species are uncommon. Harbor porpoises and harbor seals are considered to be

behaviorally sensitive species (*e.g.,* Southall *et al.,* 2007) and the effects of wind farm construction in Europe on these species have been well documented. These species have received particular attention in European waters due to their abundance in the North Sea (Hammond *et al.,* 2002; Nachtsheim *et al.,* 2021). A summary of the literature on documented effects of wind farm construction on harbor porpoise and harbor seals is described below.

Brandt *et al.* (2016) summarized the effects of the construction of eight offshore wind projects within the German North Sea (*i.e.,* Alpha Ventus, BARD Offshore I, Borkum West II, DanTysk, Global Tech I, Meerwind Süd/Ost, Nordsee Ost, and Riffgat) between 2009 and 2013 on harbor porpoises, combining passive acoustic monitoring (PAM) data from 2010 to 2013 and aerial surveys from 2009 to 2013 with data on noise levels associated with pile driving. Results of the analysis revealed significant declines in porpoise detections during pile driving when compared to 25–48 hours before pile driving began, with the magnitude of decline during pile driving clearly decreasing with increasing distances to the construction site. During the majority of projects, significant declines in detections (by at least 20 percent) were found within at least 5–10 km (3.1–6.2 mi) of the pile driving site, with declines at up to 20–30 km (12.4–18.6 mi) of the pile driving site documented in some cases. Similar results demonstrating the long-distance displacement of harbor porpoises (18–25 km; 11.1–15.5 mi) and harbor seals (up to 40 km (24.9 mi)) during impact pile driving have also been observed during the construction at multiple other European wind farms (Tougaard *et al.,* 2009; Bailey *et al.,* 2010; Dähne *et al.,* 2013; Lucke *et al.,* 2012; Haelters *et al.,* 2015).

While harbor porpoises and seals tend to move several kilometers away from wind farm construction activities, the duration of displacement has been documented to be relatively temporary. In two studies at Horns Rev II using impact pile driving, harbor porpoise returned within 1 to 2 days following cessation of pile driving (Tougaard *et al.,* 2009; Brandt *et al.,* 2011). Similar recovery periods have been noted for harbor seals off England during the construction of four wind farms (Brasseur *et al.,* 2012; Hamre *et al.,* 2011; Hastie *et al.,* 2015; Russell *et al.,* 2016). In some cases, an increase in harbor porpoise activity has been documented inside wind farm areas following construction (*e.g.,* Lindeboom *et al.,* 2011). Other studies have noted longer term impacts after impact pile driving. Near Dogger Bank in Germany, harbor porpoises continued to avoid the area for over 2 years after construction began (Gilles *et al.,* 2009). Approximately 10 years after construction of the Nysted wind farm, harbor porpoise abundance had not recovered to the original levels previously seen, although the echolocation activity was noted to have been increasing when compared to the previous monitoring period (Teilmann and Carstensen, 2012). However, overall, there are no indications for a population decline of harbor porpoises in European waters (*e.g.,* Brandt *et al.,* 2016). Notably, where significant differences in displacement and return rates have been identified for these species, the occurrence of secondary project-specific influences such as use of mitigation measures (*e.g.,* bubble curtains, acoustic deterrent devices), or the manner in which species use the habitat in the LIA, are likely the driving factors of this variation.

NMFS notes that the aforementioned European studies involved installing much smaller monopiles than Vineyard Wind proposes to install (Brandt *et al.,* 2016) and, therefore we anticipate noise levels from impact pile driving to be louder. However, we do not anticipate any greater severity of response due to harbor porpoise and harbor seal habitat use off Massachusetts or population-level consequences similar to European findings. In many cases, harbor porpoises and harbor seals are resident to the areas where European wind farms have been constructed. However, off Massachusetts, harbor porpoises and seals are more transient, and a very small percentage of the harbor seal population are only seasonally present with no rookeries established (Hayes *et al.,* 2022). In summary, we anticipate that harbor porpoise and harbor seals will likely respond to pile driving by moving several kilometers away from the source but return to typical habitat use patterns when pile driving ceases.

Some avoidance behavior of other marine mammal species has been documented to be dependent on distance from the source. As described above, DeRuiter *et al.* (2013) noted that distance from a sound source may moderate marine mammal reactions in their study of Cuvier's beaked whales (an acoustically sensitive species), which showed the whales swimming rapidly and silently away when a sonar signal was 3.4–9.5 km (2.1–5.9 mi) away while showing no such reaction to the same signal when the signal was 118 km (73.3 mi) away even though the received levels were similar. Tyack *et al.* (1983) conducted playback studies of Surveillance Towed Array Sensor System (SURTASS) low-frequency active (LFA) sonar in a gray whale migratory corridor off California. Similar to NARWs, gray whales migrate close to shore (approximately +2 km (+1.2 mi)) and are low-frequency hearing specialists. The LFA sonar source was placed within the gray whale migratory corridor (approximately 2 km (1.2 mi) offshore) and offshore of most, but not all, migrating whales (approximately 4 km (2.5 mi) offshore). These locations influenced received levels and distance to the source. For the inshore playbacks, not unexpectedly, the louder the source level of the playback (*i.e.,* the louder the received level), whale avoided the source at greater distances. Specifically, when the source levels were 170 and 178 dB rms, whales avoided the inshore source at ranges of several hundred meters, similar to avoidance responses reported by Malme *et al.* (1983, 1984). Whales exposed to source levels of 185 dB rms demonstrated avoidance levels at ranges of +1 km (+0.6 mi). Responses to the offshore source broadcasting at source levels of 185 and 200 dB, avoidance responses were greatly reduced. While there was observed deflection from course, in no case did a whale abandon its migratory behavior.

The signal context of the noise exposure has been shown to play an important role in avoidance responses. In a 2007–2008 Bahamas study, playback sounds of a potential predator—a killer whale—resulted in a similar but more pronounced reaction in beaked whales (an acoustically sensitive species), which included longer inter-dive intervals and a sustained straight-line departure of more than 20 km (12.4 mi) from the area (Boyd *et al.,* 2008; Southall *et al.,* 2009; Tyack *et al.,* 2011). In contrast, the sounds produced by pile driving activities do not have signal characteristics similar to predators. Therefore, we would not expect such extreme reactions to occur. Southall *et al.* (2011) found that blue whales had a different response to sonar exposure depending on behavioral state, more pronounced when deep feeding/travel modes than when engaged in surface feeding.

One potential consequence of behavioral avoidance is the altered energetic expenditure of marine mammals because energy is required to move and avoid surface vessels or the sound field associated with active sonar (Frid and Dill, 2002). Most animals can avoid that energetic cost by swimming away at slow speeds or speeds that

minimize the cost of transport (Miksis-Olds, 2006), as has been demonstrated in Florida manatees (Miksis-Olds, 2006). Those energetic costs increase, however, when animals shift from a resting state, which is designed to conserve an animal's energy, to an active state that consumes energy the animal would have conserved had it not been disturbed. Marine mammals that have been disturbed by anthropogenic noise and vessel approaches are commonly reported to shift from resting to active behavioral states, which would imply that they incur an energy cost.

Forney *et al.* (2017) detailed the potential effects of noise on marine mammal populations with high site fidelity, including displacement and auditory masking, noting that a lack of observed response does not imply absence of fitness costs and that apparent tolerance of disturbance may have population-level impacts that are less obvious and difficult to document. Avoidance of overlap between disturbing noise and areas and/or times of particular importance for sensitive species may be critical to avoiding population-level impacts because (particularly for animals with high site fidelity) there may be a strong motivation to remain in the area despite negative impacts. Forney *et al.* (2017) stated that, for these animals, remaining in a disturbed area may reflect a lack of alternatives rather than a lack of effects.

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, but observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Frid and Dill, 2002). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, beaked whale strandings (Cox *et al.,* 2006; D'Amico *et al.,* 2009). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response. Flight responses of marine mammals have been documented in response to mobile high intensity active sonar (*e.g.,* Tyack *et al.,* 2011; DeRuiter *et al.,* 2013; Wensveen *et al.,* 2019), and more severe responses have been documented when sources are moving towards an animal or when they are surprised by unpredictable exposures (Watkins, 1986; Falcone *et al.,* 2017). Generally speaking, however, marine mammals would be expected to be less likely to respond with a flight response to stationery pile driving (which they can sense is stationery and predictable), unless they are within the area ensonified above behavioral harassment thresholds at the moment the pile driving begins (Watkins, 1986; Falcone *et al.,* 2017).

Diving and Foraging

Changes in dive behavior in response to noise exposure can vary widely. They may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Costa *et al.,* 2003; Ng and Leung, 2003; Nowacek *et al.,* 2004; Goldbogen *et al.,* 2013a; Goldbogen *et al.,* 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. Variations in dive behavior may also expose an animal to potentially harmful conditions (*e.g.,* increasing the chance of ship-strike) or may serve as an avoidance response that enhances survivorship. The impact of a variation in diving resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure, the type and magnitude of the response, and the context within which the response occurs (*e.g.,* the surrounding environmental and anthropogenic circumstances).

Nowacek *et al.* (2004) reported disruptions of dive behaviors in foraging NARWs when exposed to an alerting stimulus, an action, they noted, that could lead to an increased likelihood of ship strike. The alerting stimulus was in the form of an 18-minute exposure that included three 2-minute signals played three times sequentially. This stimulus was designed with the purpose of providing signals distinct to background noise that serve as localization cues. However, the whales did not respond to playbacks of either right whale social sounds or vessel noise, highlighting the importance of the sound characteristics in producing a behavioral reaction. Although source levels for the proposed pile driving activities may exceed the received level of the alerting stimulus described by Nowacek *et al.* (2004), proposed mitigation strategies (further described in the Proposed Mitigation section) will reduce the severity of response to proposed pile driving activities. Converse to the behavior of NARWs, Indo-Pacific humpback dolphins have been observed to dive for longer periods of time in areas where vessels were present and/or approaching (Ng and Leung, 2003). In both of these studies, the influence of the sound exposure cannot be decoupled from the physical presence of a surface vessel, thus complicating interpretations of the relative contribution of each stimulus to the response. Indeed, the presence of surface vessels, their approach, and speed of approach, seemed to be significant factors in the response of the Indo-Pacific humpback dolphins (Ng and Leung, 2003). Low-frequency signals of the Acoustic Thermometry of Ocean Climate (ATOC) sound source were not found to affect dive times of humpback whales in Hawaiian waters (Frankel and Clark, 2000) or to overtly affect elephant seal dives (Costa *et al.,* 2003). They did, however, produce subtle effects that varied in direction and degree among the individual seals, illustrating the equivocal nature of behavioral effects and consequent difficulty in defining and predicting them.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the cessation of secondary indicators of foraging (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Nowacek *et al.,* 2004; Madsen *et al.,* 2006; Yazvenko *et al.,* 2007; Southall *et al.,* 2019b). An understanding of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal can facilitate the assessment of whether foraging disruptions are likely to incur fitness consequences (Goldbogen *et al.,* 2013b; Farmer *et al.,* 2018; Pirotta *et al.,* 2018a; Southall *et al.,* 2019a; Pirotta *et al.,* 2021).

Impacts on marine mammal foraging rates from noise exposure have been documented, though there is little data regarding the impacts of offshore turbine construction specifically. Several broader examples follow, and it is reasonable to expect that exposure to noise produced during the year that the proposed IHA would be effective could have similar impacts. Visual tracking, passive acoustic monitoring, and movement recording tags were used to

quantify sperm whale behavior prior to, during, and following exposure to airgun arrays at received levels in the range 140–160 dB at distances of 7–13 km (4.3–8.1 mi), following a phase-in of sound intensity and full array exposures at 1–13 km (0.6–8.1 mi) (Madsen *et al.,* 2006; Miller *et al.,* 2009). Sperm whales did not exhibit horizontal avoidance behavior at the surface. However, foraging behavior may have been affected. The sperm whales exhibited 19 percent less vocal (buzz) rate during full exposure relative to post exposure, and the whale that was approached most closely had an extended resting period and did not resume foraging until the airguns had ceased firing. The remaining whales continued to execute foraging dives throughout exposure; however, swimming movements during foraging dives were 6 percent lower during exposure than during control periods (Miller *et al.,* 2009). Miller *et al.* (2009) noted that more data are required to understand whether the differences were due to exposure or natural variation in sperm whale behavior. Balaenopterid whales exposed to moderate low-frequency signals similar to the ATOC sound source demonstrated no variation in foraging activity (Croll *et al.,* 2001), whereas five out of six NARWs exposed to an acoustic alarm interrupted their foraging dives (Nowacek *et al.,* 2004). Although the received SPLs were similar in the latter two studies, the frequency, duration, and temporal pattern of signal presentation were different. These factors, as well as differences in species sensitivity, are likely contributing factors to the differential response. The noise generated by Vineyard Wind's proposed activities would at least partially overlap in frequency with signals described by Nowacek *et al.* (2004) and Croll *et al.* (2001). Blue whales exposed to mid-frequency sonar in the Southern California Bight were less likely to produce low-frequency calls usually associated with feeding behavior (Melcón *et al.,* 2012). However, Melcón *et al.* (2012) were unable to determine if suppression of low-frequency calls reflected a change in their feeding performance or abandonment of foraging behavior and indicated that implications of the documented responses are unknown. Further, it is not known whether the lower rates of calling actually indicated a reduction in feeding behavior or social contact since the study used data from remotely deployed, passive acoustic monitoring buoys. Results from the 2010–2011 field season of a behavioral response study of tagged blue whales in Southern California waters indicated that, in some cases and at low received levels, the whales responded to mid-frequency sonar but that those responses were mild and there was a quick return to their baseline activity (Southall *et al.,* 2011, 2012b, 2019).

Information on or estimates of the energetic requirements of the individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal will help better inform a determination of whether foraging disruptions incur fitness consequences. Foraging strategies may impact foraging efficiency, such as by reducing foraging effort and increasing success in prey detection and capture, in turn promoting fitness and allowing individuals to better compensate for foraging disruptions. Surface feeding blue whales did not show a change in behavior in response to mid-frequency simulated and real sonar sources with received levels between 90 and 179 dB re 1 µPa, but deep feeding and non-feeding whales showed temporary reactions including cessation of feeding, reduced initiation of deep foraging dives, generalized avoidance responses, and changes to dive behavior (DeRuiter *et al.,* 2017; Goldbogen *et al.,* 2013b; Sivle *et al.,* 2015). Goldbogen *et al.* (2013b) indicate that disruption of feeding and displacement could impact individual fitness and health. However, for this to be true, we would have to assume that an individual whale could not compensate for this lost feeding opportunity by either immediately feeding at another location, by feeding shortly after cessation of acoustic exposure, or by feeding at a later time. There is no indication that individual fitness and health would be impacted by an activity that influences foraging disruption, particularly since unconsumed prey would likely still be available in the environment in most cases following the cessation of acoustic exposure.

Similarly, while the rates of foraging lunges decrease in humpback whales due to sonar exposure, there was variability in the response across individuals, with one animal ceasing to forage completely and another animal starting to forage during the exposure (Sivle *et al.,* 2016). In addition, almost half of the animals that demonstrated avoidance were foraging before the exposure, but the others were not; the animals that avoided while not feeding responded at a slightly lower received level and greater distance than those that were feeding (Wensveen *et al.,* 2017). These findings indicate the behavioral state of the animal and foraging strategies play a role in the type and severity of a behavioral response. For example, when the prey field was mapped and used as a covariate in examining how behavioral state of blue whales is influenced by mid-frequency sound, the response in blue whale deep-feeding behavior was even more apparent, reinforcing the need for contextual variables to be included when assessing behavioral responses (Friedlaender *et al.,* 2016).

Vocalizations and Auditory Masking

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, production of echolocation clicks, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result directly from increased vigilance or a startle response, or from a need to compete with an increase in background noise (see Erbe *et al.,* 2016 review on communication masking), the latter of which is described more below.

For example, in the presence of potentially masking signals, humpback whales and killer whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003; Foote *et al.,* 2004) and blue whales increased song production (Di Iorio and Clark, 2009), while NARWs have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007). In some cases, animals may cease or reduce sound production during production of aversive signals (Bowles *et al.,* 1994; Thode *et al.,* 2020; Cerchio *et al.,* 2014; McDonald *et al.,* 1995). Blackwell *et al.* (2015) showed that whales increased calling rates as soon as airgun signals were detectable before ultimately decreasing calling rates at higher received levels.

Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, or navigation) (Richardson *et al.,* 1995; Erbe and Farmer, 2000; Tyack, 2000; Erbe *et al.,* 2016; Sorensen *et al.,* 2023). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. The ability of a noise source to

mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age, or TTS hearing loss), and existing ambient noise and propagation conditions.

Masking these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations. Masking can lead to behavioral changes including vocal changes (*e.g.,* Lombard effect, increasing amplitude, or changing frequency), cessation of foraging or lost foraging opportunities, and leaving an area, to both signalers and receivers, in an attempt to compensate for noise levels (Erbe *et al.,* 2016) or because sounds that would typically have triggered a behavior were not detected. Even when animals attempt to compensate for masking, such as by increasing the amplitude or duration of their signals, this may still be insufficient to maintain behavioral coordination between individuals necessary for complex behaviors, foraging, and navigation (Sorensen *et al.,* 2023). In humans, significant masking of tonal signals occurs as a result of exposure to noise in a narrow band of similar frequencies. As the sound level increases, the detection of frequencies above those of the masking stimulus decreases. This principle is expected to apply to marine mammals as well because of common biomechanical cochlear properties across taxa.

Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting behavioral patterns. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which only occurs during the sound exposure. Because masking (without resulting in threshold shift) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009; Matthews, 2017) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013; Cholewiak *et al.,* 2018).

The echolocation calls of toothed whales are subject to masking by high-frequency sound. Human data indicate low-frequency sound can mask high-frequency sounds (*i.e.,* upward masking). Studies on captive odontocetes by Au *et al.* (1974, 1985, 1993) indicate that some species may use various processes to reduce masking effects (*e.g.,* adjustments in echolocation call intensity or frequency as a function of background noise conditions). There is also evidence that the directional hearing abilities of odontocetes are useful in reducing masking at the high-frequencies these cetaceans use to echolocate, but not at the low-to-moderate frequencies they use to communicate (Zaitseva *et al.,* 1980). A study by Nachtigall and Supin (2008) showed that false killer whales adjust their hearing to compensate for ambient sounds and the intensity of returning echolocation signals.

Impacts on signal detection, measured by masked detection thresholds, are not the only important factors to address when considering the potential effects of masking. As marine mammals use sound to recognize conspecifics, prey, predators, or other biologically significant sources (Branstetter *et al.,* 2016), it is also important to understand the impacts of masked recognition thresholds (often called ''informational masking''). Branstetter *et al.* (2016) measured masked recognition thresholds for whistle-like sounds of bottlenose dolphins and observed that they are approximately 4 dB above detection thresholds (energetic masking) for the same signals. Reduced ability to recognize a conspecific call or the acoustic signature of a predator could have severe negative impacts. Branstetter *et al.* (2016) observed that if ''quality communication'' is set at 90 percent recognition the output of communication space models (which are based on 50 percent detection) would likely result in a significant decrease in communication range.

As marine mammals use sound to recognize predators (Allen *et al.,* 2014; Cummings and Thompson, 1971; Curé *et al.,* 2015; Fish and Vania, 1971), the presence of masking noise may also prevent marine mammals from responding to acoustic cues produced by their predators, particularly if it occurs in the same frequency band. For example, harbor seals that reside in the coastal waters off British Columbia are frequently targeted by mammal-eating killer whales. The seals acoustically discriminate between the calls of mammal-eating and fish-eating killer whales (Deecke *et al.,* 2002), a capability that should increase survivorship while reducing the energy required to attend to all killer whale calls. Similarly, sperm whales (Curé *et al.,* 2016; Isojunno *et al.,* 2016), long-finned pilot whales (Visser *et al.,* 2016), and humpback whales (Curé *et al.,* 2015) changed their behavior in response to killer whale vocalization playbacks; these findings indicate that some recognition of predator cues could be missed if the killer whale vocalizations were masked. The potential effects of masked predator acoustic cues depend on the duration of the masking noise and the likelihood of a marine mammal encountering a predator during the time that detection and recognition of predator cues are impeded.

Redundancy and context can also facilitate detection of weak signals. These phenomena may help marine mammals detect weak sounds in the presence of natural or manmade noise. Most masking studies in marine mammals present the test signal and the masking noise from the same direction. The dominant background noise may be highly directional if it comes from a particular anthropogenic source such as a ship or industrial site. Directional hearing may significantly reduce the masking effects of these sounds by improving the effective signal-to-noise ratio.

Masking affects both senders and receivers of acoustic signals and, at higher levels and longer duration, can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times

in terms of sound pressure level (SPL)) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009; Cholewiak *et al.,* 2018). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from commercial vessel traffic), contribute to elevated ambient sound levels, thus intensifying masking.

In addition to making it more difficult for animals to perceive and recognize acoustic cues in their environment, anthropogenic sound presents separate challenges for animals that are vocalizing. When they vocalize, animals are aware of environmental conditions that affect the ''active space'' (or communication space) of their vocalizations, which is the maximum area within which their vocalizations can be detected before it drops to the level of ambient noise (Brenowitz, 2004; Brumm *et al.,* 2004; Lohr *et al.,* 2003). Animals are also aware of environmental conditions that affect whether listeners can discriminate and recognize their vocalizations from other sounds, which is more important than simply detecting that a vocalization is occurring (Brenowitz, 1982; Brumm *et al.,* 2004; Dooling, 2004; Marten and Marler, 1977; Patricelli and Blickley, 2006). Most species that vocalize have evolved with an ability to adjust their vocalizations to increase the signal-to-noise ratio, active space, and recognizability/distinguishability of their vocalizations in the face of temporary changes in background noise (Brumm *et al.,* 2004; Patricelli and Blickley, 2006). Vocalizing animals can adjust their vocalization characteristics such as the frequency structure, amplitude, temporal structure, and temporal delivery (repetition rate), or ceasing to vocalize.

Many animals will combine several of these strategies to compensate for high levels of background noise. Anthropogenic sounds that reduce the signal-to-noise ratio of animal vocalizations; increase the masked auditory thresholds of animals listening for such vocalizations; or reduce the active space of an animal's vocalizations impair communication between animals. Most animals that vocalize have evolved strategies to compensate for the effects of short-term or temporary increases in background or ambient noise on their songs or calls. Although the fitness consequences of these vocal adjustments are not directly known in all instances, like most other trade-offs animals must make, some of these strategies likely come at a cost (Patricelli and Blickley, 2006; Noren *et al.,* 2017; Noren *et al.,* 2020). Shifting songs and calls to higher frequencies may also impose energetic costs (Lambrechts, 1996).

Marine mammals are also known to make vocal changes in response to anthropogenic noise. In cetaceans, vocalization changes have been reported from exposure to anthropogenic noise sources such as sonar, vessel noise, and seismic surveying (*e.g.,* Gordon *et al.,* 2003; Di Iorio and Clark, 2009; Hatch *et al.,* 2012; Holt *et al.,* 2009, 2011; Lesage *et al.,* 1999; McDonald *et al.,* 2009; Parks *et al.,* 2007; Risch *et al.,* 2012; Rolland *et al.,* 2012), as well as changes in the natural acoustic environment (Dunlop *et al.,* 2014). Vocal changes can be temporary or can be persistent. For example, model simulation suggests that the increase in starting frequency for the NARW upcall over the last 50 years resulted in increased detection ranges between right whales. The frequency shift, coupled with an increase in call intensity by 20 dB, led to a call detectability range of less than 3 km (1.9 mi) to over 9 km (5.6 mi) (Tennessen and Parks, 2016). Holt *et al.* (2009) measured killer whale call source levels and background noise levels in the 1 to 40 kHz band and reported that the whales increased their call source levels by 1-dB SPL for every 1-dB SPL increase in background noise level. Similarly, another study on St. Lawrence River belugas reported a similar rate of increase in vocalization activity in response to passing vessels (Scheifele *et al.,* 2005). Di Iorio and Clark (2009) showed that blue whale calling rates vary in association with seismic sparker survey activity, with whales calling more on days with surveys than on days without surveys. They suggested that the whales called more during seismic survey periods as a way to compensate for the elevated noise conditions.

In some cases, these vocal changes may have fitness consequences, such as an increase in metabolic rates and oxygen consumption, as observed in bottlenose dolphins when increasing their call amplitude (Holt *et al.,* 2015). A switch from vocal communication to physical, surface-generated sounds such as pectoral fin slapping or breaching was observed for humpback whales in the presence of increasing natural background noise levels, indicating that adaptations to masking may also move beyond vocal modifications (Dunlop *et al.,* 2010).

While these changes all represent possible tactics by the sound-producing animal to reduce the impact of masking, the receiving animal can also reduce masking by using active listening strategies such as orienting to the sound source, moving to a quieter location, or reducing self-noise from hydrodynamic flow by remaining still. The temporal structure of noise (*e.g.,* amplitude modulation) may also provide a considerable release from masking through comodulation masking release (a reduction of masking that occurs when broadband noise, with a frequency spectrum wider than an animal's auditory filter bandwidth at the frequency of interest, is amplitude modulated) (Branstetter and Finneran, 2008; Branstetter *et al.,* 2013). Signal type (*e.g.,* whistles, burst-pulse, sonar clicks) and spectral characteristics (*e.g.,* frequency modulated with harmonics) may further influence masked detection thresholds (Branstetter *et al.,* 2016; Cunningham *et al.,* 2014).

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources, such as vessels. Several studies have shown decreases in marine mammal communication space and changes in behavior as a result of the presence of vessel noise. For example, right whales were observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007) as well as increasing the amplitude (intensity) of their calls (Parks, 2009, 2011). Clark *et al.* (2009) observed that right whales' communication space decreased by up to 84 percent in the presence of vessels due to an increase in ambient noise from vessels in proximity to the whales. Cholewiak *et al.* (2018) also observed loss in communication space in Stellwagen National Marine Sanctuary for NARWs, fin whales, and humpback whales with increased ambient noise and shipping noise. Although humpback whales off Australia did not change the frequency or duration of their vocalizations in the presence of ship noise, their source levels were lower than expected based on source level changes to wind noise, potentially indicating some signal masking (Dunlop, 2016). Multiple delphinid species have also been shown to increase the minimum or maximum frequencies of their whistles in the presence of anthropogenic noise and reduced communication space (*e.g.,* Holt *et al.,* 2009, 2011; Gervaise *et al.,* 2012; Williams *et al.,* 2013; Hermannsen *et al.,* 2014; Papale *et al.,* 2015; Liu *et al.,* 2017). While masking impacts are not a concern from lower intensity, higher frequency HRG surveys, some degree of masking would be expected in the vicinity of turbine pile driving and concentrated support vessel operation.

However, pile driving is an intermittent sound and would not be continuous throughout the day.

Habituation and Sensitization

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). Habituation is considered a ''progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,'' rather than as, more generally, moderation in response to human disturbance having a neutral or positive outcome (Bejder *et al.,* 2009). Animals are most likely to habituate to sounds that are predictable and unvarying. The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

Both habituation and sensitization require an ongoing learning process. As noted, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.,* 1995; National Research Council (NRC), 2003; Wartzok *et al.,* 2003; Southall *et al.,* 2019b). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (*e.g.,* Ridgway *et al.,* 1997; Finneran *et al.,* 2003; Houser *et al.,* 2013a–b; Kastelein *et al.,* 2018). Observed responses of wild marine mammals to loud impulsive sound sources (typically airguns or acoustic harassment devices) have been varied but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; Richardson *et al.,* 1995; Nowacek *et al.,* 2007; Tougaard *et al.,* 2009; Brandt *et al.,* 2011, 2012, 2014, 2018; Dähne *et al.,* 2013; Russell *et al.,* 2016).

Stone (2015) reported data from at-sea observations during 1,196 airgun surveys from 1994 to 2010. When large arrays of airguns (considered to be 500 cubic inches (in^3) or more) were firing, lateral displacement, more localized avoidance, or other changes in behavior were evident for most odontocetes. However, significant responses to large arrays were found only for the minke whale and fin whale. Behavioral responses observed included changes in swimming or surfacing behavior with indications that cetaceans remained near the water surface at these times. Behavioral observations of gray whales during an airgun survey monitored whale movements and respirations before, during, and after seismic surveys (Gailey *et al.,* 2016). Behavioral state and water depth were the best ''natural'' predictors of whale movements and respiration, and after accounting for natural variation, none of the response variables were significantly associated with survey or vessel sounds. Many delphinids approach low-frequency airgun source vessels with no apparent discomfort or obvious behavioral change (*e.g.,* Barkaszi *et al.,* 2012), indicating the importance of frequency output in relation to the species' hearing sensitivity.

Physiological Responses

An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (*e.g.,* Selye, 1950; Moberg and Mench, 2000). In many cases, an animal's first, and sometimes most economical response (in terms of energetic costs) is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (*e.g.,* Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.,* 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and ''distress'' is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficiently to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well studied through controlled experiments and for both laboratory and free-ranging animals (*e.g.,* Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied specifically in wild populations (*e.g.,* Lusseau and Bejder, 2007; Romano *et al.,* 2002a; Rolland *et al.,* 2012). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in NARWs.

These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003, 2017). Respiration naturally varies with different behaviors, and variations in respiration rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Mean exhalation rates of gray whales at rest and while diving were found to be unaffected by seismic surveys conducted adjacent to the whale feeding grounds (Gailey *et al.,* 2007). Studies with captive harbor porpoises show increased respiration rates upon introduction of acoustic alarms (Kastelein *et al.,* 2001, 2006a) and emissions for underwater data transmission (Kastelein *et al.,* 2005). However, exposure of the same acoustic alarm to a striped dolphin under the same conditions did not elicit a response (Kastelein *et al.,* 2006a), again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure.

Stranding

The definition for a stranding under the MMPA is that: (A) a marine mammal is dead and is (i) on a beach or shore

of the United States, or (ii) in waters under the jurisdiction of the United States (including any navigable waters); or (B) a marine mammal is alive and is (i) on a beach or shore of the United States and is unable to return to the water, (ii) on a beach or shore of the United States and, although able to return to the water, is in need of apparent medical attention, or (iii) in the waters under the jurisdiction of the United States (including any navigable waters), but is unable to return to its natural habitat under its own power or without assistance (16 U.S.C. 1421h).

Marine mammal strandings have been linked to a variety of causes, such as illness from exposure to infectious agents, biotoxins, or parasites; starvation; unusual oceanographic or weather events; or anthropogenic causes including fishery interaction, ship strike, entrainment, entrapment, sound exposure, or combinations of these stressors sustained concurrently or in series. There have been multiple events worldwide in which marine mammals (primarily beaked whales, or other deep divers) have stranded coincident with relatively nearby activities utilizing loud sound sources (primarily military training events), and five in which mid-frequency active sonar has been more definitively determined to have been a contributing factor.

There are multiple theories regarding the specific mechanisms responsible for marine mammal strandings caused by exposure to loud sounds. One primary theme is the behaviorally mediated responses of deep-diving species (odontocetes), in which their startled response to an acoustic disturbance: (1) affects ascent or descent rates, the time they stay at depth or the surface, or other regular dive patterns that are used to physiologically manage gas formation and absorption within their bodies, such that the formation or growth of gas bubbles damages tissues or causes other injury; or (2) results in their flight to shallow areas, enclosed bays, or other areas considered ''out of habitat,'' in which they become disoriented and physiologically compromised. For more information on marine mammal stranding events and potential causes, please see the Stranding and Mortality discussion in NMFS' proposed rule for the Navy's Training and Testing Activities in the Hawaii-Southern California Training and Testing Study Area (83 FR 29872, 29928; June 26, 2018).

The construction activities proposed by Vineyard Wind (*i.e.,* pile driving) are not expected to result in marine mammal strandings. Of the strandings documented to date worldwide, NMFS is not aware of any being attributed to pile driving. While vessel strikes could kill or injure a marine mammal (which may then eventually strand), the required mitigation measures would reduce the potential for take from these activities to de minimis levels (see Proposed Mitigation section for more details). As described above, no mortality or serious injury is anticipated or proposed to be authorized from any Project activities.

Potential Effects of Disturbance on Marine Mammal Fitness

The different ways that marine mammals respond to sound are sometimes indicators of the ultimate effect that exposure to a given stimulus will have on the well-being (survival, reproduction, *etc.*) of an animal. There are numerous data relating the exposure of terrestrial mammals from sound to effects on reproduction or survival, and data for marine mammals continues to grow. Several authors have reported that disturbance stimuli may cause animals to abandon nesting and foraging sites (Sutherland and Crockford, 1993); may cause animals to increase their activity levels and suffer premature deaths or reduced reproductive success when their energy expenditures exceed their energy budgets (Daan *et al.,* 1996; Feare, 1976; Mullner *et al.,* 2004); or may cause animals to experience higher predation rates when they adopt risk-prone foraging or migratory strategies (Frid and Dill, 2002). Each of these studies addressed the consequences of animals shifting from one behavioral state (*e.g.,* resting or foraging) to another behavioral state (*e.g.,* avoidance or escape behavior) because of human disturbance or disturbance stimuli.

Attention is the cognitive process of selectively concentrating on one aspect of an animal's environment while ignoring other things (Posner, 1994). Because animals (including humans) have limited cognitive resources, there is a limit to how much sensory information they can process at any time. The phenomenon called ''attentional capture'' occurs when a stimulus (usually a stimulus that an animal is not concentrating on or attending to) ''captures'' an animal's attention. This shift in attention can occur consciously or subconsciously (for example, when an animal hears sounds that it associates with the approach of a predator) and the shift in attention can be sudden (Dukas, 2002; van Rij, 2007). Once a stimulus has captured an animal's attention, the animal can respond by ignoring the stimulus, assuming a ''watch and wait'' posture, or treat the stimulus as a disturbance and respond accordingly, which includes scanning for the source of the stimulus or ''vigilance'' (Cowlishaw *et al.,* 2004).

Vigilance is an adaptive behavior that helps animals determine the presence or absence of predators, assess their distance from conspecifics, or to attend cues from prey (Bednekoff and Lima, 1998; Treves, 2000). Despite those benefits, however, vigilance has a cost of time; when animals focus their attention on specific environmental cues, they are not attending to other activities such as foraging or resting. These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (Saino, 1994; Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). Animals will spend more time being vigilant, which may translate to less time foraging or resting, when disturbance stimuli approach them more directly, remain at closer distances, have a greater group size (*e.g.,* multiple surface vessels), or when they co-occur with times that an animal perceives increased risk (*e.g.,* when they are giving birth or accompanied by a calf).

The primary mechanism by which increased vigilance and disturbance appear to affect the fitness of individual animals is by disrupting an animal's time budget and, as a result, reducing the time they might spend foraging and resting (which increases an animal's activity rate and energy demand while decreasing their caloric intake/energy). In a study of northern resident killer whales off Vancouver Island, exposure to boat traffic was shown to reduce foraging opportunities and increase traveling time (Holt *et al.,* 2021). A simple bioenergetics model was applied to show that the reduced foraging opportunities equated to a decreased energy intake of 18 percent while the increased traveling incurred an increased energy output of 3–4 percent, which suggests that a management action based on avoiding interference with foraging might be particularly effective.

On a related note, many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant for fitness if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than 1

day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). It is important to note the difference between behavioral reactions lasting or recurring over multiple days and anthropogenic activities lasting or recurring over multiple days. For example, just because certain activities last for multiple days does not necessarily mean that individual animals will be either exposed to those activity-related stressors (*i.e.,* sonar) for multiple days or further exposed in a manner that would result in sustained multi-day substantive behavioral responses. However, special attention is warranted where longer-duration activities overlay areas in which animals are known to congregate for longer durations for biologically important behaviors.

There are few studies that directly illustrate the impacts of disturbance on marine mammal populations. Lusseau and Bejder (2007) present data from three long-term studies illustrating the connections between disturbance from whale-watching boats and population-level effects in cetaceans. In Shark Bay, Australia, the abundance of bottlenose dolphins was compared within adjacent control and tourism sites over three consecutive 4.5-year periods of increasing tourism levels. Between the second and third time periods, in which tourism doubled, dolphin abundance decreased by 15 percent in the tourism area and did not change significantly in the control area. In Fiordland, New Zealand, two populations (Milford and Doubtful Sounds) of bottlenose dolphins with tourism levels that differed by a factor of seven were observed and significant increases in traveling time and decreases in resting time were documented for both. Consistent short-term avoidance strategies were observed in response to tour boats until a threshold of disturbance was reached (average of 68 minutes between interactions), after which the response switched to a longer-term habitat displacement strategy. For one population, tourism only occurred in a part of the home range. However, tourism occurred throughout the home range of the Doubtful Sound population and once boat traffic increased beyond the 68-minute threshold (resulting in abandonment of their home range/preferred habitat), reproductive success drastically decreased (increased stillbirths) and abundance decreased significantly (from 67 to 56 individuals in a short period).

In order to understand how the effects of activities may or may not impact species and stocks of marine mammals, it is necessary to understand not only what the likely disturbances are going to be but how those disturbances may affect the reproductive success and survivorship of individuals, and then how those impacts to individuals translate to population-level effects. Following on the earlier work of a committee of the U.S. NRC (NRC, 2005), New *et al.* (2014), in an effort termed the Potential Consequences of Disturbance (PCoD), outlined an updated conceptual model of the relationships linking disturbance to changes in behavior and physiology, health, vital rates, and population dynamics. This framework is a four-step process progressing from changes in individual behavior and/or physiology, to changes in individual health, then vital rates, and finally to population-level effects. In this framework, behavioral and physiological changes can have direct (acute) effects on vital rates, such as when changes in habitat use or increased stress levels raise the probability of mother-calf separation or predation; indirect and long-term (chronic) effects on vital rates, such as when changes in time/energy budgets or increased disease susceptibility affect health, which then affects vital rates; or no effect to vital rates (New *et al.,* 2014).

Since the PCoD general framework was outlined and the relevant supporting literature compiled, multiple studies developing state-space energetic models for species with extensive long-term monitoring (*e.g.,* southern elephant seals, NARWs, Ziphiidae beaked whales, and bottlenose dolphins) have been conducted and can be used to effectively forecast longer-term, population-level impacts from behavioral changes. While these are very specific models with very specific data requirements that cannot yet be applied broadly to project-specific risk assessments for the majority of species, they are a critical first step towards being able to quantify the likelihood of a population level effect. Since New *et al.* (2014), several publications have described models developed to examine the long-term effects of environmental or anthropogenic disturbance of foraging on various life stages of selected species (*e.g.,* sperm whale, Farmer *et al.,* 2018; California sea lion, McHuron *et al.,* 2018; blue whale, Pirotta *et al.,* 2018a; humpback whale, Dunlop *et al.,* 2021). These models continue to add to refinement of the approaches to the PCoD framework. Such models also help identify what data inputs require further investigation. Pirotta *et al.* (2018b) provides a review of the PCoD framework with details on each step of the process and approaches to applying real data or simulations to achieve each step.

Despite its simplicity, there are few complete PCoD models available for any marine mammal species due to a lack of data available to parameterize many of the steps. To date, no PCoD model has been fully parameterized with empirical data (Pirotta *et al.,* 2018a) due to the fact they are data intensive and logistically challenging to complete. Therefore, most complete PCoD models include simulations, theoretical modeling, and expert opinion to move through the steps. For example, PCoD models have been developed to evaluate the effect of wind farm construction on the North Sea harbor porpoise populations (*e.g.,* King *et al.,* 2015; Nabe-Nielsen *et al.,* 2018). These models include a mix of empirical data, expert elicitation (King *et al.,* 2015) and simulations of animals' movements, energetics, and/or survival (New *et al.,* 2014; Nabe-Nielsen *et al.,* 2018).

PCoD models may also be approached in different manners. Dunlop *et al.* (2021) modeled migrating humpback whale mother-calf pairs in response to seismic surveys using both a forwards and backwards approach. While a typical forwards approach can determine if a stressor would have population-level consequences, Dunlop *et al.* demonstrated that working backwards through a PCoD model can be used to assess the most unfavorable scenario for an interaction of a target species and stressor. This method may be useful for future management goals when appropriate data becomes available to fully support the model. In another example, harbor porpoise PCoD model investigating the impact of seismic surveys on harbor porpoise included an investigation on underlying drivers of vulnerability. Harbor porpoise movement and foraging were modeled for baseline periods and then for periods with seismic surveys as well; the models demonstrated that temporal (*i.e.,* seasonal) variation in individual energetics and their link to costs associated with disturbances was key in predicting population impacts (Gallagher *et al.,* 2021).

Behavioral change, such as disturbance manifesting in lost foraging time, in response to anthropogenic activities is often assumed to indicate a biologically significant effect on a population of concern. However, as described above, individuals may be able to compensate for some types and degrees of shifts in behavior, preserving their health and thus their vital rates and population dynamics. For example,

New *et al.* (2013) developed a model simulating the complex social, spatial, behavioral, and motivational interactions of coastal bottlenose dolphins in the Moray Firth, Scotland, to assess the biological significance of increased rate of behavioral disruptions caused by vessel traffic. Despite a modeled scenario in which vessel traffic increased from 70 to 470 vessels a year (a six-fold increase in vessel traffic) in response to the construction of a proposed offshore renewables' facility, the dolphins' behavioral time budget, spatial distribution, motivations, and social structure remain unchanged. Similarly, two bottlenose dolphin populations in Australia were also modeled over 5 years against a number of disturbances (Reed *et al.,* 2020), and results indicated that habitat/noise disturbance had little overall impact on population abundances in either location, even in the most extreme impact scenarios modeled.

By integrating different sources of data (*e.g.,* controlled exposure data, activity monitoring, telemetry tracking, and prey sampling) into a theoretical model to predict effects from sonar on a blue whale's daily energy intake, Pirotta *et al.* (2021) found that tagged blue whales' activity budgets, lunging rates, and ranging patterns caused variability in their predicted cost of disturbance. This method may be useful for future management goals when appropriate data becomes available to fully support the model. Harbor porpoise movement and foraging were modeled for baseline periods and then for periods with seismic surveys as well; the models demonstrated that the seasonality of the seismic activity was an important predictor of impact (Gallagher *et al.,* 2021).

In their table 1, Keen *et al.* (2021) summarize the emerging themes in PCoD models that should be considered when assessing the likelihood and duration of exposure and the sensitivity of a population to disturbance (see table 1 from Keen *et al.,* 2021, below). The themes are categorized by life history traits (movement ecology, life history strategy, body size, and pace of life), disturbance source characteristics (overlap with biologically important areas, duration and frequency, and nature and context), and environmental conditions (natural variability in prey availability and climate change). Keen *et al.* (2021) then summarize how each of these features influence an assessment, noting, for example, that individual animals with small home ranges have a higher likelihood of prolonged or year-round exposure, that the effect of disturbance is strongly influenced by whether it overlaps with biologically important habitats when individuals are present, and that continuous disruption will have a greater impact than intermittent disruption.

Nearly all PCoD studies and experts agree that infrequent exposures of a single day or less are unlikely to impact individual fitness, let alone lead to population level effects (Booth *et al.,* 2016; Booth *et al.,* 2017; Christiansen and Lusseau, 2015; Farmer *et al.,* 2018; Wilson *et al.,* 2020; Harwood and Booth, 2016; King *et al.,* 2015; McHuron *et al.,* 2018; National Academies of Sciences, Engineering, and Medicine (NAS), 2017; New *et al.,* 2014; Pirotta *et al.,* 2018a; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015). As described through this notice for the proposed IHA, NMFS expects that any behavioral disturbance that would occur due to animals being exposed to construction activity would be of a relatively short duration, with behavior returning to a baseline state shortly after the acoustic stimuli ceases or the animal moves far enough away from the source. Given this, and NMFS' evaluation of the available PCoD studies, and the required mitigation discussed later, any such behavioral disturbance resulting from Vineyard Wind's activities is not expected to impact individual animals' health or have effects on individual animals' survival or reproduction, thus no detrimental impacts at the population level are anticipated. Marine mammals may temporarily avoid the immediate area but are not expected to permanently abandon the area or their migratory or foraging behavior. Impacts to breeding, feeding, sheltering, resting, or migration are not expected nor are shifts in habitat use, distribution, or foraging success.

Potential Effects From Vessel Strike

Vessel collisions with marine mammals, also referred to as vessel strikes or ship strikes, can result in death or serious injury of the animal. Wounds resulting from ship strike may include massive trauma, hemorrhaging, broken bones, or propeller lacerations (Knowlton and Kraus, 2001). An animal at the surface could be struck directly by a vessel, a surfacing animal could hit the bottom of a vessel, or an animal just below the surface could be cut by a vessel's propeller. Superficial strikes may not kill or result in the death of the animal. Lethal interactions are typically associated with large whales, which are occasionally found draped across the bulbous bow of large commercial ships upon arrival in port. Although smaller cetaceans are more maneuverable in relation to large vessels than are large whales, they may also be susceptible to strike. The severity of injuries typically depends on the size and speed of the vessel (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Vanderlaan and Taggart, 2007; Conn and Silber, 2013), although Kelley *et al.* (2020) found, through the use of a simple biophysical model, that large whales can be seriously injured or killed by vessels of all sizes. Impact forces increase with speed, as does the probability of a strike at a given distance (Silber *et al.,* 2010; Gende *et al.,* 2011).

The most vulnerable marine mammals are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slow-moving whales. Marine mammal responses to vessels may include avoidance and changes in dive pattern (NRC, 2003).

An examination of all known ship strikes from all shipping sources (civilian and military) indicates vessel speed is a principal factor in whether a vessel strike occurs and, if so, whether it results in injury, serious injury, or mortality (Knowlton and Kraus, 2001; Laist *et al.,* 2001; Jensen and Silber, 2003; Pace and Silber, 2005; Vanderlaan and Taggart, 2007; Conn and Silber, 2013). In assessing records in which vessel speed was known, Laist *et al.* (2001) found a direct relationship between the occurrence of a whale strike and the speed of the vessel involved in the collision. The authors concluded that most deaths occurred when a vessel was traveling in excess of 13 kn.

Jensen and Silber (2003) detailed 292 records of known or probable ship strikes of all large whale species from 1975 to 2002. Of these, vessel speed at the time of collision was reported for 58 cases. Of these 58 cases, 39 (or 67 percent) resulted in serious injury or death (19 of those resulted in serious injury as determined by blood in the water, propeller gashes or severed tailstock, and fractured skull, jaw, vertebrae, hemorrhaging, massive bruising, or other injuries noted during necropsy and 20 resulted in death). Operating speeds of vessels that struck various species of large whales ranged from 2 to 51 kn. The majority (79 percent) of these strikes occurred at speeds of 13 kn or greater. The average speed that resulted in serious injury or death was 18.6 kn. Pace and Silber (2005) found that the probability of death or serious injury increased rapidly with increasing vessel speed.

Specifically, the predicted probability of serious injury or death increased from 45 to 75 percent as vessel speed increased from 10 to 14 kn and exceeded 90 percent at 17 kn. Higher speeds during collisions result in greater force of impact and also appear to increase the chance of severe injuries or death. While modeling studies have suggested that hydrodynamic forces pulling whales toward the vessel hull increase with increasing speed (Clyne, 1999; Knowlton *et al.,* 1995), this is inconsistent with Silber *et al.* (2010), which demonstrated that there is no such relationship (*i.e.,* hydrodynamic forces are independent of speed).

In a separate study, Vanderlaan and Taggart (2007) analyzed the probability of lethal mortality of large whales at a given speed, showing that the greatest rate of change in the probability of a lethal injury to a large whale as a function of vessel speed occurs between 8.6 and 15 kn. The chances of a lethal injury decline from approximately 80 percent at 15 kn to approximately 20 percent at 8.6 kn. At speeds below 11.8 kn, the chances of lethal injury drop below 50 percent, while the probability asymptotically increases toward 100 percent above 15 kn.

The Jensen and Silber (2003) report notes that the Large Whale Ship Strike Database represents a minimum number of collisions, because the vast majority probably goes undetected or unreported. In contrast, the Project's personnel are likely to detect any strike that does occur because of the required personnel training and lookouts, along with the inclusion of PSOs (as described in the Proposed Mitigation section), and they are required to report all ship strikes involving marine mammals.

There are no known vessel strikes of marine mammals by any offshore wind energy vessel in the United States. Given the extensive mitigation and monitoring measures (see the Proposed Mitigation and Proposed Monitoring and Reporting section) that would be required of Vineyard Wind, NMFS believes that a vessel strike is not likely to occur.

Potential Effects to Marine Mammal Habitat

Vineyard Wind's proposed activities could potentially affect marine mammal habitat through impacts on the prey species of marine mammals (through noise, oceanographic processes, or reef effects), acoustic habitat (sound in the water column), water quality, and biologically important habitat for marine mammals.

Effects on Prey

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, and zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick and Mann, 1999; Fay, 2009). The most likely effects on fishes exposed to loud, intermittent, low-frequency sounds are behavioral responses (*i.e.,* flight or avoidance). Short duration, sharp sounds (such as pile driving or airguns) can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to acoustic sources depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality. While it is clear that the behavioral responses of individual prey, such as displacement or other changes in distribution, can have direct impacts on the foraging success of marine mammals, the effects on marine mammals of individual prey that experience hearing damage, barotrauma, or mortality is less clear, though obviously population scale impacts that meaningfully reduce the amount of prey available could have more serious impacts.

Fishes, like other vertebrates, have a variety of different sensory systems to glean information from ocean around them (Astrup and Mohl, 1993; Astrup, 1999; Braun and Grande, 2008; Carroll *et al.,* 2017; Hawkins and Johnstone, 1978; Ladich and Popper, 2004; Ladich and Schulz-Mirbach, 2016; Mann, 2016; Nedwell *et al.,* 2004; Popper *et al.,* 2003, 2005). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008) (terrestrial vertebrates generally only detect pressure). Most marine fishes primarily detect particle motion using the inner ear and lateral line system while some fishes possess additional morphological adaptations or specializations that can enhance their sensitivity to sound pressure, such as a gas-filled swim bladder (Braun and Grande, 2008; Popper and Fay, 2011).

Hearing capabilities vary considerably between different fish species with data only available for just over 100 species out of the 34,000 marine and freshwater fish species (Eschmeyer and Fong, 2016). In order to better understand acoustic impacts on fishes, fish hearing groups are defined by species that possess a similar continuum of anatomical features, which result in varying degrees of hearing sensitivity (Popper and Hastings, 2003). There are four hearing groups defined for all fish species (modified from Popper *et al.,* 2014) within this analysis, and they include: fishes without a swim bladder (*e.g.,* flatfish, sharks, rays, *etc.*); fishes with a swim bladder not involved in hearing (*e.g.,* salmon, cod, pollock, *etc.*); fishes with a swim bladder involved in hearing (*e.g.,* sardines, anchovy, herring, *etc.*); and fishes with a swim bladder involved in hearing and high-frequency hearing (*e.g.,* shad and menhaden). Most marine mammal fish prey species would not be likely to perceive or hear mid- or high-frequency sonars. While hearing studies have not been done on sardines and northern anchovies, it would not be unexpected for them to have hearing similarities to Pacific herring (up to 2–5 kHz) (Mann *et al.,* 2005). Currently, less data are available to estimate the range of best sensitivity for fishes without a swim bladder.

In terms of physiology, multiple scientific studies have documented a lack of mortality or physiological effects to fish from exposure to low- and mid-frequency sonar and other sounds (Halvorsen *et al.,* 2012a; Jørgensen *et al.,* 2005; Juanes *et al.,* 2017; Kane *et al.,* 2010; Kvadsheim and Sevaldsen, 2005; Popper *et al.,* 2007, 2016; Watwood *et al.,* 2016). Techer *et al.* (2017) exposed carp in floating cages for up to 30 days to low-power 23 and 46 kHz source without any significant physiological response. Other studies have documented either a lack of TTS in species whose hearing range cannot perceive sonar (such as Navy sonar), or for those species that could perceive sonar-like signals, any TTS experienced would be recoverable (Halvorsen *et al.,* 2012a; Ladich and Fay, 2013; Popper and Hastings, 2009a, 2009b; Popper *et al.,* 2014; Smith, 2016). Only fishes that have specializations that enable them to hear sounds above about 2,500 Hz (2.5 kHz), such as herring (Halvorsen *et al.,* 2012a; Mann *et al.,* 2005; Mann, 2016; Popper *et al.,* 2014), would have the potential to receive TTS or exhibit behavioral responses from exposure to

mid-frequency sonar. In addition, any sonar induced TTS to fish whose hearing range could perceive sonar would only occur in the narrow spectrum of the source (*e.g.,* 3.5 kHz) compared to the fish's total hearing range (*e.g.,* 0.01 to 5 kHz).

In terms of behavioral responses, Juanes *et al.* (2017) discuss the potential for negative impacts from anthropogenic noise on fish, but the authors' focus was on broader based sounds, such as ship and boat noise sources. Watwood *et al.* (2016) also documented no behavioral responses by reef fish after exposure to mid-frequency active sonar. Doksaeter *et al.* (2009, 2012) reported no behavioral responses to mid-frequency sonar (such as naval sonar) by Atlantic herring; specifically, no escape reactions (vertically or horizontally) were observed in free swimming herring exposed to mid-frequency sonar transmissions. Based on these results (Doksaeter *et al.,* 2009, 2012; Sivle *et al.,* 2012), Sivle *et al.* (2014) created a model in order to report on the possible population-level effects on Atlantic herring from active sonar. The authors concluded that the use of sonar poses little risk to populations of herring regardless of season, even when the herring populations are aggregated and directly exposed to sonar. Finally, Bruintjes *et al.* (2016) commented that fish exposed to any short-term noise within their hearing range might initially startle but would quickly return to normal behavior.

Pile driving noise during construction is of particular concern as the very high sound pressure levels could potentially prevent fish from reaching breeding or spawning sites, finding food, and acoustically locating mates. A playback study in west Scotland revealed that there was a significant movement response to the pile driving stimulus in both species at relatively low received sound pressure levels (sole: 144–156 dB re 1µPa Peak; cod: 140–161 dB re 1 µPa Peak, particle motion between 6.51×10^3 and 8.62×10^4 m/s^2 peak) (Mueller-Blenkle *et al.,* 2010). The swimming speed of sole increased significantly during the playback of construction noise when compared to the playbacks of before and after construction. While not statistically significant, cod also displayed a similar behavioral response during before, during, and after construction playbacks. However, cod demonstrated a specific and significant freezing response at the onset and cessation of the playback recording. In both species, indications were present displaying directional movements away from the playback source. During wind farm construction in the eastern Taiwan Strait, type 1 soniferous fish chorusing showed a relatively lower intensity and longer duration while type 2 chorusing exhibited higher intensity and no changes in its duration. Deviation from regular fish vocalization patterns may affect fish reproductive success, cause migration, augmented predation, or physiological alterations.

Occasional behavioral reactions to activities that produce underwater noise sources are unlikely to cause long-term consequences for individual fish or populations. The most likely impact to fish from impact and vibratory pile driving activities at the LIAs would be temporary behavioral avoidance of the area. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. The duration of fish avoidance of an area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected.

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As described in the Proposed Mitigation section below, Vineyard Wind would utilize a sound attenuation device which would reduce potential for injury to marine mammal prey. Other fish that experience hearing loss as a result of exposure to impulsive sound sources may have a reduced ability to detect relevant sounds such as predators, prey, or social vocalizations. However, PTS has not been known to occur in fishes and any hearing loss in fish may be as temporary as the timeframe required to repair or replace the sensory cells that were damaged or destroyed (Popper *et al.,* 2005, 2014; Smith, 2006). It is not known if damage to auditory nerve fibers could occur, and if so, whether fibers would recover during this process. In addition, most acoustic effects, if any, are expected to be short-term and localized. Long-term consequences for fish populations, including key prey species within the LIA, would not be expected.

Required soft-starts would allow prey and marine mammals to move away from the source prior to any noise levels that may physically injure prey and the use of the noise attenuation devices would reduce noise levels to the degree any mortality or injury of prey is also minimized. Use of bubble curtains, in addition to reducing impacts to marine mammals, for example, is a key mitigation measure in reducing injury and mortality of ESA-listed salmon on the U.S. west coast. However, we recognize some mortality, physical injury and hearing impairment in marine mammal prey may occur, but we anticipate the amount of prey impacted in this manner is minimal compared to overall availability. Any behavioral responses to pile driving by marine mammal prey are expected to be brief. We expect that other impacts, such as stress or masking, would occur in fish that serve as marine mammals prey (Popper *et al.,* 2019); however, those impacts would be limited to the duration of impact pile driving, and, if prey were to move out the area in response to noise, these impacts would be minimized.

In addition to fish, prey sources such as marine invertebrates could potentially be impacted by noise stressors as a result of the proposed activities. However, most marine invertebrates' ability to sense sounds is limited. Invertebrates appear to be able to detect sounds (Pumphrey, 1950; Frings and Frings, 1967) and are most sensitive to low-frequency sounds (Packard *et al.,* 1990; Budelmann and Williamson, 1994; Lovell *et al.,* 2005; Mooney *et al.,* 2010). Data on response of invertebrates such as squid, another marine mammal prey species, to anthropogenic sound is more limited (de Soto, 2016; Sole *et al.,* 2017). Data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect airgun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Sole *et al.* (2017) reported physiological injuries to cuttlefish in cages placed at-sea when exposed during a controlled exposure experiment to low-frequency sources (315 Hz, 139 to 142 dB re 1 µPa^2; 400 Hz, 139 to 141 dB re 1 µPa^2).

Fewtrell and McCauley (2012) reported squids maintained in cages displayed startle responses and behavioral changes when exposed to seismic airgun sonar (136–162 re 1 $\mu Pa^2 \times s$). Jones *et al.* (2020) found that when squid (*Doryteuthis pealeii*) were exposed to impulse pile driving noise, body pattern changes, inking, jetting, and startle responses were observed and nearly all squid exhibited at least one response. However, these responses occurred primarily during the first eight impulses and diminished quickly, indicating potential rapid, short-term habituation.

Cephalopods have a specialized sensory organ inside the head called a statocyst that may help an animal determine its position in space (orientation) and maintain balance (Budelmann, 1992). Packard *et al.* (1990) showed that cephalopods were sensitive to particle motion, not sound pressure, and Mooney *et al.* (2010) demonstrated that squid statocysts act as an accelerometer through which particle motion of the sound field can be detected. Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000; Samson *et al.,* 2014). Squids, like most fish species, are likely more sensitive to low-frequency sounds and may not perceive mid- and high-frequency sonars.

With regard to potential impacts on zooplankton, McCauley *et al.* (2017) found that exposure to airgun noise resulted in significant depletion for more than half the taxa present and that there were two to three times more dead zooplankton after airgun exposure compared with controls for all taxa, within 1 km (0.6 mi) of the airguns. However, the authors also stated that in order to have significant impacts on r-selected species (*i.e.,* those with high growth rates and that produce many offspring) such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned, and it is possible that the findings reflect avoidance by zooplankton rather than mortality (McCauley *et al.,* 2017). In addition, the results of this study are inconsistent with a large body of research that generally finds limited spatial and temporal impacts to zooplankton as a result of exposure to airgun noise (*e.g.,* Dalen and Knutsen, 1987; Payne, 2004; Stanley *et al.,* 2011). Most prior research on this topic, which has focused on relatively small spatial scales, has showed minimal effects (*e.g.,* Kostyuchenko, 1973; Booman *et al.,* 1996; Sætre and Ona, 1996; Pearson *et al.,* 1994; Bolle *et al.,* 2012).

A modeling exercise was conducted as a follow-up to the McCauley *et al.* (2017) study (as recommended by McCauley *et al.,* 2017), in order to assess the potential for impacts on ocean ecosystem dynamics and zooplankton population dynamics (Richardson *et al.,* 2017). Richardson *et al.* (2017) found that a full-scale airgun survey would impact copepod abundance within the survey area, but that effects at a regional scale were minimal (2 percent decline in abundance within 150 km (93.2 mi) of the survey area and effects not discernible over the full region). The authors also found that recovery within the survey area would be relatively quick (3 days following survey completion) and suggest that the quick recovery was due to the fast growth rates of zooplankton, and the dispersal and mixing of zooplankton from both inside and outside of the impacted region. The authors also suggest that surveys in areas with more dynamic ocean circulation in comparison with the study region and/or with deeper waters (*i.e.,* typical offshore wind locations) would have less net impact on zooplankton.

Notably, a recently described study produced results inconsistent with those of McCauley *et al.* (2017). Researchers conducted a field and laboratory study to assess if exposure to airgun noise affects mortality, predator escape response, or gene expression of the copepod *Calanus finmarchicus* (Fields *et al.,* 2019). Immediate mortality of copepods was significantly higher, relative to controls, at distances of 5 m or less from the airguns. Mortality 1 week after the airgun blast was significantly higher in the copepods placed 10 m from the airgun but was not significantly different from the controls at a distance of 20 m from the airgun. The increase in mortality, relative to controls, did not exceed 30 percent at any distance from the airgun. Moreover, the authors caution that even this higher mortality in the immediate vicinity of the airguns may be more pronounced than what would be observed in free-swimming animals due to increased flow speed of fluid inside bags containing the experimental animals. There were no sub-lethal effects on the escape performance, or the sensory threshold needed to initiate an escape response, at any of the distances from the airgun that were tested. Whereas McCauley *et al.* (2017) reported an SEL of 156 dB at a range of 509–658 m, with zooplankton mortality observed at that range, Fields *et al.* (2019) reported an SEL of 186 dB at a range of 25 m, with no reported mortality at that distance.

Airguns and impact pile driving are similar in that they both produce impulsive and intermittent noise and typically have higher source levels than other sources (*e.g.,* vibratory driving). We anticipate marine mammal prey exposed to impact pile driving would demonstrate similar physical consequences and behavioral impacts compared to exposure to airguns; however, the spatial extent of these impacts during impact pile driving is dependent upon source levels and use of noise attenuation systems (NAS) such as double bubble curtains, such that lower source levels and use of NAS are expected to further minimize impacts that would occur otherwise.

The presence of large numbers of turbines has been shown to impact meso- and sub-meso-scale water column circulation, which can affect the density, distribution, and energy content of zooplankton and thereby, their availability as marine mammal prey. Topside, atmospheric wakes result in wind speed reductions influencing upwelling and downwelling in the ocean while underwater structures such as WTG and ESP foundations may cause turbulent current wakes, which impact circulation, stratification, mixing, and sediment resuspension (Daewel *et al.,* 2022). Overall, the presence of structures such as wind turbines is, in general, likely to result in certain oceanographic effects in the marine environment and may alter marine mammal prey, such as aggregations and distribution of zooplankton through changing the strength of tidal currents and associated fronts, changes in stratification, primary production, the degree of mixing, and stratification in the water column (Chen *et al.,* 2021; Johnson *et al.,* 2021; Christiansen *et al.,* 2022; Dorrell *et al.,* 2022).

Turbine operations for the previously installed 47 WTG monopile foundations commenced in 2023. Vineyard Wind intends to install 15 WTG monopile foundations, and it is possible that turbines would become operational by the end of the IHA effective period. As described below (see *Potential Effects from Offshore Wind Farm Operational Noise* section), there is scientific uncertainty around the scale of oceanographic impacts (meters to kilometers) associated with turbine operation. The Project is located offshore of Massachusetts, and although the LIA does overlap with key winter

foraging grounds for NARWs (Leiter *et al.,* 2017; Quintana-Rizzo *et al.,* 2021; O'Brien *et al.,* 2022; Pendleton *et al.,* 2022), nearby habitat may provide higher foraging value should NARW prey be affected in the LIA during construction, and the amount of pile driving time with only 15 piles remaining to be installed is expected to be limited, thereby limiting potential impacts on prey aggregation. In addition, the proposed seasonal restriction on pile driving from January through May would reduce impacts to NARW prey during the time that they are more likely to be foraging. The LIA does not overlap but is in proximity to seasonal foraging grounds for fin whales, minke whales, and sei whales. Generally speaking, and depending on the extent, impacts on prey could impact the distribution of marine mammals in an area, potentially necessitating additional energy expenditure to find and capture prey. However, at the temporal and spatial scales anticipated for this activity, any such impacts on prey are not expected to impact the reproduction or survival of any individual marine mammals. Although studies assessing the impacts of offshore wind development on marine mammals are limited, the repopulation of wind energy areas by harbor porpoises (Brandt *et al.,* 2016; Lindeboom *et al.,* 2011) and harbor seals (Lindeboom *et al.,* 2011; Russell *et al.,* 2016) following the installation of wind turbines are promising. Overall, any impacts to marine mammal foraging capabilities due to effects on prey aggregation from the turbine presence and operation during the effective period of the proposed IHA is likely to be limited. In general, impacts to marine mammal prey species are expected to be relatively minor and temporary due to the expected short daily duration of individual pile driving events and the relatively small areas being affected.

Reef Effects

The presence of monopile foundations and scour protection will result in a conversion of the existing sandy bottom habitat to a hard bottom habitat with areas of vertical structural relief. This could potentially alter the existing habitat by creating an ''artificial reef effect'' that results in colonization by assemblages of both sessile and mobile animals within the new hard-bottom habitat (Wilhelmsson *et al.,* 2006; Reubens *et al.,* 2013; Bergström *et al.,* 2014; Coates *et al.,* 2014). This colonization by marine species, especially hard-substrate preferring species, can result in changes to the diversity, composition, and/or biomass of the area thereby impacting the trophic composition of the site (Wilhelmsson *et al.,* 2010; Krone *et al.,* 2013; Bergström *et al.,* 2014; Hooper *et al.,* 2017; Raoux *et al.,* 2017; Harrison and Rousseau, 2020; Taormina *et al.,* 2020; Buyse *et al.,* 2022a; ter Hofstede *et al.,* 2022).

Artificial structures can create increased habitat heterogeneity important for species diversity and density (Langhamer, 2012). The monopile WTG foundations will extend through the water column, which may serve to increase settlement of meroplankton or planktonic larvae on the structures in both the pelagic and benthic zones (Boehlert and Gill, 2010). Fish and invertebrate species are also likely to aggregate around the foundations and scour protection which could provide increased prey availability and structural habitat (Boehlert and Gill, 2010; Bonar *et al.,* 2015). Further, instances of species previously unknown, rare, or nonindigenous to an area have been documented at artificial structures, changing the composition of the food web and possibly the attractability of the area to new or existing predators (Adams *et al.,* 2014; de Mesel, 2015; Bishop *et al.,* 2017; Hooper *et al.,* 2017; Raoux *et al.,* 2017; van Hal *et al.,* 2017; Degraer *et al.,* 2020; Fernandez-Betelu *et al.,* 2022). Notably, there are examples of these sites becoming dominated by marine mammal prey species, such as filter-feeding species and suspension-feeding crustaceans (Andersson and Öhman, 2010; Slavik *et al.,* 2019; Hutchison *et al.,* 2020; Pezy *et al.,* 2020; Mavraki *et al.,* 2022).

Numerous studies have documented significantly higher fish concentrations including species like cod and pouting (*Trisopterus luscus*), flounder (*Platichthys flesus*), eelpout (*Zoarces viviparus*), and eel (*Anguilla anguilla*) near in-water structures than in surrounding soft bottom habitat (Langhamer and Wilhelmsson, 2009; Bergström *et al.,* 2013; Reubens *et al.,* 2013). In the German Bight portion of the North Sea, fish were most densely congregated near the anchorages of jacket foundations, and the structures extending through the water column were thought to make it more likely that juvenile or larval fish encounter and settle on them (Rhode Island Coastal Resources Management Council, 2010; Krone *et al.,* 2013). In addition, fish can take advantage of the shelter provided by these structures while also being exposed to stronger currents created by the structures, which generate increased feeding opportunities and decreased potential for predation (Wilhelmsson *et al.,* 2006). The presence of the foundations and resulting fish aggregations around the foundations is expected to be a long-term habitat impact, but the increase in prey availability could potentially be beneficial for some marine mammals.

Water Quality

Temporary and localized reduction in water quality will occur as a result of pile driving activities. These activities will disturb bottom sediments and may cause a temporary increase in suspended sediment in the LIA. Currents should quickly dissipate any raised total suspended sediment (TSS) levels, and levels should return to background levels once the project activities in that area cease. No direct impacts on marine mammals are anticipated due to increased TSS and turbidity; however, turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the LIA. However, turbidity plumes associated with the project would be temporary and localized, and fish in the LIA would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary.

Equipment used by Vineyard Wind within the LIA, including ships and other marine vessels, potentially aircrafts, and other equipment, are also potential sources of by-products (*e.g.,* hydrocarbons, particulate matter, heavy metals). All equipment is properly maintained in accordance with applicable legal requirements. All such operating equipment meets Federal water quality standards, where applicable. Given these requirements, impacts to water quality are expected to be minimal.

Acoustic Habitat

Acoustic habitat is the soundscape, which encompasses all of the sound present in a particular location and time, as a whole when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural

contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are defined and influenced by the total contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic or may be intentionally introduced to the marine environment for data acquisition purposes (as in the use of airgun arrays) or for Navy training and testing purposes (as in the use of sonar and explosives and other acoustic sources). Anthropogenic noise varies widely in its frequency, content, duration, and loudness. These characteristics greatly influence the potential habitat-mediated effects to marine mammals (please also see the previous discussion on Masking), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). For more detail on these concepts, see: Barber *et al.,* 2009; Pijanowski *et al.,* 2011; Francis and Barber, 2013; Lillis *et al.,* 2014.

The term ''listening area'' refers to the region of ocean over which sources of sound can be detected by an animal at the center of the space. Loss of communication space concerns the area over which a specific animal signal, used to communicate with conspecifics in biologically important contexts (*e.g.,* foraging, mating), can be heard, in noisier relative to quieter conditions (Clark *et al.,* 2009). Lost listening area concerns the more generalized contraction of the range over which animals would be able to detect a variety of signals of biological importance, including eavesdropping on predators and prey (Barber *et al.,* 2009). Such metrics do not, in and of themselves, document fitness consequences for the marine animals that live in chronically noisy environments. Long-term population-level consequences mediated through changes in the ultimate survival and reproductive success of individuals are difficult to study, and particularly so underwater. However, it is increasingly well documented that aquatic species rely on qualities of natural acoustic habitats, with researchers quantifying reduced detection of important ecological cues (*e.g.,* Francis and Barber, 2013; Slabbekoorn *et al.,* 2010) as well as survivorship consequences in several species (*e.g.,* Simpson *et al.,* 2014; Nedelec *et al.,* 2014).

Potential Effects From Offshore Wind Farm Operational Noise

Although this proposed IHA primarily covers the noise produced from construction activities relevant to the Vineyard Wind Offshore Wind Project offshore wind facility, operational noise was a consideration in NMFS' analysis of the project, as turbines may become operational within the effective dates of the IHA (if issued).

In both newer, quieter, direct-drive systems and older generation, geared turbine designs, recent scientific studies indicate that operational noise from turbines is on the order of 110 to 125 dB re 1 µPa root-mean-square sound pressure level (SPL_{rms}) at an approximate distance of 50 m (Tougaard *et al.,* 2020). Recent measurements of operational sound generated from wind turbines (direct drive, 6 MW, jacket foundations) at Block Island wind farm (BIWF) indicate average broadband levels of 119 dB at 50 m from the turbine, with levels varying with wind speed (HDR, *Inc.,* 2019). Interestingly, measurements from BIWF turbines showed operational sound had fewer tonal components compared to European measurements of turbines with gear boxes.

Tougaard *et al.* (2020) further stated that the operational noise produced by WTGs is static in nature and lower than noise produced by passing ships. This is a noise source in this region to which marine mammals are likely already habituated. Furthermore, operational noise levels are likely lower than those ambient levels already present in active shipping lanes, such that operational noise would likely only be detected in very close proximity to the WTG (Thomsen *et al.,* 2006; Tougaard *et al.,* 2020). Similarly, recent measurements from a wind farm (3–MW turbines) in China found that above 300 Hz, turbines produced sound that was similar to background levels (Zhang *et al.,* 2021). Other studies by Jansen and de Jong (2016) and Tougaard *et al.* (2009) determined that, while marine mammals would be able to detect operational noise from offshore wind farms (again, based on older 2–MW models) for several kilometers, they expected no significant impacts on individual survival, population viability, marine mammal distribution, or the behavior of the animals considered in their study (harbor porpoises and harbor seals). In addition, Madsen *et al.* (2006) found the intensity of noise generated by operational wind turbines to be much less than the noises present during construction, although this observation was based on a single turbine with a maximum power of 2 MW.

More recently, Stöber and Thomsen (2021) used monitoring data and modeling to estimate noise generated by more recently developed, larger (10–MW) direct-drive WTGs. Their findings, similar to Tougaard *et al.* (2020), demonstrate that there is a trend that operational noise increases with turbine size. Their study predicts broadband source levels could exceed 170-dB SPL_{rms} for a 10–MW WTG; however, those noise levels were generated based on geared turbines whereas newer turbines operate with direct drive technology. The shift from using gear boxes to direct drive technology is expected to reduce the levels by 10 dB. The findings in the Stöber and Thomsen (2021) study have not been experimentally validated, though the modeling (using largely geared turbines) performed by Tougaard *et al.* (2020) yields similar results for a hypothetical 10–MW WTG.

Recently, Holme *et al.* (2023) cautioned that the Tougaard *et al.* (2020) and Stöber and Thomsen (2021) studies extrapolated levels for larger turbines should be interpreted with caution since both studies relied on data from smaller turbines (0.45 to 6.15 MW) collected over a variety of environmental conditions. Holme et al. (2023) demonstrated that the model presented in Tougaard *et al.* (2020) tends to potentially overestimate levels (up to approximately 8 dB) measured to those in the field, especially with measurements closer to the turbine for larger turbines. Holme *et al.* (2023) measured operational noise from larger turbines (6.3 and 8.3 MW) associated with three wind farms in Europe and found no relationship between turbine activity (power production, which is proportional to the blade's revolutions per minute) and noise level, though it was noted that this missing relationship may have been masked by the area's relatively high ambient noise sound levels. Sound levels (rms) of a 6.3–MW direct-drive turbine were measured to be 117.3 dB at a distance of 70 m. However, measurements from 8.3 MW turbines were inconclusive as turbine noise was deemed to have been largely masked by ambient noise.

Finally, operational turbine measurements are available from the Coastal Virginia Offshore Wind (CVOW)

pilot pile project, where two 7.8 m monopile WTGs were installed (HDR, 2023). Compared to BIWF, levels at CVOW were higher (10–30 dB) below 120 Hz, believed to be caused by the vibrations associated with the monopile structure, while above 120 Hz levels were consistent among the two wind farms.

Overall, noise from operating turbines would raise ambient noise levels in the immediate vicinity of the turbines; however, the spatial extent of increased noise levels would be limited. Vineyard Wind did not request, and NMFS is not proposing to authorize, take incidental to operational noise from WTGs. Therefore, the topic is not discussed or analyzed further herein. However, NMFS proposes to require Vineyard Wind to measure operational noise levels.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the IHA, which will inform NMFS' consideration of ''small numbers,'' the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which: (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Proposed takes would primarily be by Level B harassment, as noise from pile driving has the potential to result in disruption of marine mammal behavioral patterns. Impacts such as masking and TTS can contribute to the disruption of behavioral patterns and are accounted for within those takes proposed for authorization. There is also some potential for high frequency species (harbor porpoise) and phocids (harbor seal and gray seal) to experience a limited amount of auditory injury (PTS; Level A harassment) primarily because predicted auditory injury zones are large enough and these species are cryptic enough that the potential for PTS cannot be fully discounted. For mysticetes, the Level A harassment $ER95_{percent}$ ranges are also large (0.0043 km to 3.191 km); however, the extensive marine mammal mitigation and monitoring proposed by Vineyard Wind, and which would be required by NMFS, as well as natural avoidance behaviors is expected to reduce the potential for PTS to discountable levels. Nevertheless, Vineyard Wind has requested, and NMFS proposes to authorize a small amount of Level A harassment incidental to installing piles (table 11). Auditory injury is unlikely to occur for mid-frequency species as thresholds are higher and PTS zones are very close to the pile such that PTS is unlikely to occur. While NMFS is proposing to authorize Level A harassment and Level B harassment, the proposed mitigation and monitoring measures are expected to, in some cases, avoid,and minimize overall the severity of the taking to the extent practicable (see Proposed Mitigation and Proposed Monitoring and Reporting sections).

As described previously, no serious injury or mortality is anticipated or proposed to be authorized incidental to the specified activity. Even without mitigation, pile driving activities are unlikely to directly cause marine mammal mortality or serious injury. There is no documented case wherein pile driving resulted in marine mammal mortality or stranding and the scientific literature demonstrates that the most likely behavioral response to pile driving (or similar stimulus source) is avoidance and temporary cessation of behaviors such as foraging or socialization (see *Avoidance and Displacement* in Potential Effects of Specified Activities on Marine Mammals and Their Habitat section). While, in general, there is a low probability that mortality or serious injury of marine mammals could occur from vessel strikes, the mitigation and monitoring measures contained within this proposed rule are expected to avoid vessel strikes (see Proposed Mitigation section). No other activities have the potential to result in mortality or serious injury.

For acoustic impacts, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

As described below, there are multiple methods available to estimate the density or number of a given species in the area appropriate to inform the take estimate. For each species and activity, the largest value resulting from the three take estimation methods described below (*i.e.,* density-based, PSO-based, or mean group size) was carried forward as the amount of take proposed for authorization, by Level B harassment. The amount of take proposed for authorization, by Level A harassment, reflects the density-based exposure estimates and, for some species and activities, consideration of other data such as mean group size.

Below, we describe NMFS' acoustic thresholds, acoustic and exposure modeling methodologies, marine mammal density calculation methodology, occurrence information, and the modeling and methodologies applied to estimate take for the Project's proposed construction activities. NMFS considered all information and analysis presented by Vineyard Wind, as well as all other applicable information and, based on the best available science, concurs that the estimates of the types and amounts of take for each species and stock are reasonable, and is proposing to authorize the amount requested. NMFS notes the take estimates described herein for foundation installation can be considered conservative because the estimates do not reflect the implementation of clearance and shutdown zones for any marine mammal species or stock.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals are likely to be behaviorally harassed (Level B harassment) or to incur PTS of some degree (Level A harassment). A summary of all NMFS' thresholds can be found at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

Level B Harassment

Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise

ratio, distance to the source, ambient noise, and the receiving animal's hearing, motivation, experience, demography, behavior at time of exposure, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment.

NMFS generally predicts that marine mammals are likely to be taken in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μPa)) for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μPa for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at closer distances from the source. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

The proposed Project's construction activities include the use of impulsive sources (*e.g.,* impact pile driving), and therefore the 160-dB re 1 μPa (rms) threshold is applicable to our analysis.

Level A Harassment

NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0, Technical Guidance; NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). As described above, Vineyard Wind's proposed activities include the use of impulsive sources. NMFS' thresholds identifying the onset of PTS are provided in table 5. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 5—PTS ONSET THRESHOLDS

[NMFS, 2018]

Hearing group	PTS onset thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	$L_{p,0\text{-}pk,flat}$: 219 dB; $L_{E,p,\ LF,24h}$: 183 dB	$L_{E,p,\ LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	$L_{p,0\text{-}pk,flat}$: 230 dB; $L_{E,p,\ MF,24h}$: 185 dB	$L_{E,p,\ MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	$L_{p,0\text{-}pk,flat}$: 202 dB; $L_{E,p,HF,24h}$: 155 dB	$L_{E,p,\ HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	$L_{p,0\text{-}pk,flat}$: 218 dB; $L_{E,p,PW,24h}$: 185 dB	$L_{E,p,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	$L_{p,0\text{-}pk,flat}$: 232 dB; $L_{E,p,OW,24h}$: 203 dB	$L_{E,p,OW,24h}$: 219 dB.

* Dual metric thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds are recommended for consideration.

Note: Peak sound pressure level ($L_{p,0\text{-}pk}$) has a reference value of 1 μPa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1μPa^2s. In this table, thresholds are abbreviated to be more reflective of International Organization for Standardization standards (ISO, 2017). The subscript ''flat'' is being included to indicate peak sound pressure are flat weighted or unweighted within the generalized hearing range of marine mammals (*i.e.,* 7 Hz to 160 kHz). The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The weighted cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these thresholds will be exceeded.

Below, we describe the assumptions and methodologies used to estimate take, in consideration of acoustic thresholds and appropriate marine mammals density and occurrence information, for WTG monopile installation. Resulting distances to thresholds, densities and occurrence (*i.e.,* PSO sightings, group size) data used, exposure estimates (as relevant to the analysis), and activity-specific take estimates can be found below.

Acoustic and Exposure Modeling

During the 2023 Vineyard Wind pile installation activities, Vineyard Wind conducted a sound field verification (SFV) study to compare with model results of the 2018 modeling (Küsel *et al.,* 2024). The SFV study included acoustic monitoring of the impact installation of 12 monopile foundations from June 6 through September 7, 2023. Five of the 12 acoustically monitored monopiles were determined to be representative of the noise attenuation system (NAS) configuration and maintenance schedule that would be proposed for the remaining 15 monopiles to be installed in 2024. These five representative monopiles (piles 7, 8, 10, 11, and 12 in the Vineyard Wind SFV Monitoring Report) were monitored using a double bubble curtain (DBBC) and Hydrosound Damper System (HSD), which has been proposed for use as the noise attenuation system setup for the remaining 15 monopiles. Vineyard Wind also followed an enhanced bubble curtain maintenance schedule for these five monopiles; this maintenance schedule would also be used for the remaining 15 monopiles to be installed in 2024 (see the Vineyard Wind Enhanced BBC Technical Memo). Peak (pk), SEL, and RMS SPL received distances for each acoustically monitored pile are reported in the VW1 SFV Final Report Appendix A (Küsel *et al.,* 2024) For additional details on how acoustic ranges were derived from SFV measurements, see the VW1 SFV Final Report sections 2.3 and 3.3 (Küsel *et al.,* 2024). JASCO modeled a maximum

range to the Level A harassment threshold of 3.191 km (1.99 mi) with 6-dB attenuation (for low-frequency cetaceans) (Küsel *et al.,* 2024).

In addition to the 15 piles being installed under the same noise attenuation scenario as the 5 aforementioned representative piles, they are also anticipated to be installed under similar pile driving specifications and in a similar acoustic environment. Table 6 describes the key piling assumptions and proposed impact pile driving schedule for 2024. These assumptions and schedule are based upon the 2023 piling and hammer energy schedule for installing monopiles. Vineyard Wind expects installation of the 15 remaining piles will necessitate similar operations. Further, as described in detail in section 6.1 of Vineyard Wind's application, the water depth and bottom type are similar throughout the Lease Area and therefore sound propagation in the LIA is not expected to differ from where the SFV data were collected in 2023.

TABLE 6—KEY PILING ASSUMPTIONS AND HAMMER ENERGY SCHEDULE FOR MONOPILE INSTALLATION

Pile type	Project component	Max hammer energy (kJ)	Number of hammer strikes	Max piling time duration per pile (min)	Number piles/day
9.6-m monopile	WTG	4,000	2,884–4,329 (average 3,463) [a]	117	1

[a] The number of hammer strikes represent the range of strikes needed to install the 12 monopiles for which SFV was conducted in 2023.

Vineyard Wind compared the acoustic ranges to the Level A harassment and Level B harassment thresholds derived from the 2018 acoustic modeling (Pyć *et al.,* 2018) to the maximum ranges with absorption for the five representative monopiles acoustically monitored in 2023. They applied the greater results to the analysis in their application and NMFS has included that approach in this proposed IHA. The maximum measured range to PTS thresholds of the five representative monopiles was less than the maximum 2018 modeled ranges for all hearing groups, assuming 6 dB of attenuation (table 7), with the exception of high-frequency cetaceans (although Vineyard Wind attributes this extended range to non-piling noise (Vineyard Wind, 2023)). Therefore, Vineyard Wind based the expected distance to the Level A harassment threshold and associated estimated take analysis on the 2018 modeled data.

TABLE 7—MODELED AND MEASURED RANGES TO SEL_{cum} PTS THRESHOLDS FOR MARINE MAMMAL HEARING GROUPS

Marine mammal hearing group	Modeled range to SEL_{cum} PTS threshold (km) [a]	Measured maximum range to SEL_{cum} PTS threshold (km) [b]
Low-frequency cetaceans	3.191	2.37
Mid-frequency cetaceans	0.043	0.01
High-frequency cetaceans	0.071	0.2
Phocid pinnipeds	0.153	0.1

[a] Based upon modeling conducted for the 2023 IHA (Pyć *et al.,* 2018)
[b] Based upon the five representative monopiles from the Vineyard Wind 2023 construction campaign (Küsel *et al.,* 2024).

The maximum range with absorption to the Level B harassment threshold for acoustically monitored piles was 5.72 km (3.6 mi) (pile 13, AU–38; Küsel *et al.,* 2024), which was greater than the 2018 modeled distance to the Level B harassment threshold of 4.1 km (2.5 mi) (Pyć *et al.,* 2018). Therefore, Vineyard Wind based the expected distance to the Level B harassment threshold and associated estimated take analysis on the 5.72-km acoustically monitored distance.

In 2018, Vineyard Wind conducted animat modeling to estimate take, by Level A harassment (PTS), incidental to the project. In order to best evaluate the SEL_{cum} harassment thresholds for PTS, it is necessary to consider animal movement, as the results are based on how sound moves through the environment between the source and the receiver. Applying animal movement and behavior within the modeled noise fields provides the exposure range, which allows for a more realistic indication of the distances at which PTS acoustic thresholds are reached that considers the accumulation of sound over different durations (note that in all cases the distance to the peak threshold is less than the SEL-based threshold). As described above, Vineyard Wind based the Level A harassment estimated take analysis on the modeled Level A harassment acoustic ranges and therefore appropriately used the results of the JASCO's Animal Simulation Model Including Noise Exposure (JASMINE) animal movement modeling conducted for the 2023 IHA (86 FR 33810, June 25, 2021). Sound exposure models like JASMINE use simulated animals (also known as ''animats'') to forecast behaviors of animals in new situations and locations based upon previously documented behaviors of those animals. The predicted 3D sound fields (*i.e.,* the output of the acoustic modeling process described earlier) are sampled by animats using movement rules derived from animal observations. The output of the simulation is the exposure history for each animat within the simulation. The precise location of animats and their pathways are not known prior to a project; therefore, a repeated random sampling technique (*i.e.,* Monte Carlo) is used to estimate exposure probability with many animats and randomized starting positions. The combined exposure history of all animats gives a probability density function of exposure during the Project.

Since the time that the JASMINE animal movement modeling was conducted for the 2023 IHA (86 FR 33810, June 25, 2021), no new behavior data is available that would have changed how animats move in time and space in that model and, therefore, NMFS has determined that the JASMINE outputs from the 2018 modeling effort are reasonable for application here. However, the post processing calculations used more recent density data (table 8). The mean

number of modeled animats exposed per day with installation of one 9.6-m monopile were scaled by the maximum monthly density for the LIA (Roberts *et al.,* 2023) for each species (table 8) to estimate the real-world number of animats of each species that could be exposed per day in the LIA. This real-world number of animals was multiplied by the expected number of days of pile installation (15 days) to derive a total take estimate by Level A harassment for each species. The number of potential exposures by Level A harassment was estimated for each species using the following equation:

Density-based exposure estimate of Level A harassment = number of animats exposed above the Level A harassment threshold× ((mean maximum monthly density (animals/km^2)/modeled 2018 density (animats/km^2))×number of days (15).

To estimate the amount of take by Level B harassment incidental to installing the remaining 15 piles, Vineyard Wind applied a static method (*i.e.,* did not conduct animal movement modeling). Vineyard Wind calculated the Level B harassment ensonified area using the following equation:

$A = 3.14 \times r^2$,

where A is equal to the ensonified area and r is equal to the radial distance to the Level B harassment threshold from the pile driving source ($r_{\text{Level B harassment}}$ = 5.72 km).

The ensonified area (102.7 km^2) was multiplied by the mean maximum monthly density estimate (table 8) and expected number of days of pile driving (15 days) to determine a density-based take estimate for each species. The number of potential exposures by Level B harassment was estimated for each species using the following equation:

Density-based exposure estimate of Level B harassment = ensonified area (km^2) × maximum mean monthly density estimate (animals/km^2) × number of days (15).

Density and Occurrence and Take Estimation

In this section we provide information about marine mammal density, presence, and group dynamics that informed the take calculations for the proposed activities. Vineyard Wind applied the 2022 Duke University Marine Geospatial Ecology Laboratory Habitat-based Marine Mammal Density Models for the U.S. Atlantic (Duke Model-Roberts *et al.,* 2016, 2023) to estimate take from foundation installation. The models estimate absolute density (individuals/km^2) by statistically correlating sightings reported on shipboard and aerial surveys with oceanographic conditions. For most marine mammal species, densities are provided on a monthly basis. Where monthly densities are not available (*e.g.,* pilot whales), annual densities are provided. Moreover, some species are represented as guilds (*e.g.,* seals (representing *Phocidae* spp., primarily harbor and gray seals) and pilot whales (representing short-finned and long-finned pilot whales)).

The Duke habitat-based density models delineate species' density into 5 × 5 km (3.1 × 3.1 mi) grid cells. Vineyard Wind calculated mean monthly densities by using a 10-km buffered polygon around the remaining WTG foundations to be installed and overlaying this buffered polygon on the density maps. The 10-km buffer defines the area around the LIA used to calculate mean species density. Mean monthly density for each species was determined by calculating the unweighted mean of all 5 × 5 km grid cells (partially or fully) within the buffered polygon. The unweighted mean refers to using the entire 5 × 5 km (3.1 × 3.1 mi) grid cell for each cell used in the analysis, and was not weighted by the proportion of the cell overlapping with the density perimeter if the entire grid cell was not entirely within the buffer zone polygon. Vineyard Wind calculated densities for each month, except for species for which annual density data only was available (*e.g.,* long-finned pilot whale). Vineyard Wind used maximum monthly density from June to December for density-based calculations.

The density models (Roberts *et al.,* 2023) provided density for pilot whales and seals as guilds. Based upon habitat and ranging patterns (Hayes *et al.,* 2023), all pilot whales occurring in the LIA are expected to be long-finned pilot whales. Therefore, all pilot whale density estimates are assumed to represent long-finned pilot whales. Seal guild density was divided into species-specific densities based upon the proportions of each species observed by PSOs during 2016 and 2018–2021 site characterizations surveys within SNE (ESS Group, 2016; Vineyard Wind 2018, 2019, 2023a–f). Of the 181 seals identified to species and sighted within the WDA, 162 were gray seals and 19 were harbor seals. The equation below shows how the proportion of each seal species sighted was calculated to compute density for seals.

$P_{\text{seal species}} = N_{\text{seal species}}/\text{Number}_{\text{total seals identified}}$,

where P represents density and N represents number of seals.

These calculations resulted in proportions of 0.895 for gray seals and 0.105 for harbor seals. The proportion for each species was then multiplied by the maximum monthly density for the seal guild (table 8) to determine the species-specific densities used in take calculations.

The density models (Roberts *et al.,* 2023) also do not distinguish between bottlenose dolphin stocks and only provide densities for bottlenose dolphins as a species. However, as described above, based upon ranging patterns (Hayes *et al.,* 2023), only the Western North Atlantic offshore stock of bottlenose dolphins is expected to occur in the LIA. Therefore, it is expected that the bottlenose dolphin density estimate is entirely representative of this stock. Maximum mean monthly density estimates and month of the maximum estimate is provided in table 8 below.

TABLE 8—MAXIMUM MEAN MONTHLY MARINE MAMMAL DENSITY ESTIMATES (ANIMALS PER km^2) CONSIDERING A 10-km BUFFER AROUND THE LIMITED INSTALLATION AREA

Species	Maximum mean density	Maximum density month
NARW *	0.0043	December.
Fin whale *	0.0036	July.
Humpback whale	0.0022	June.
Minke whale	0.018	June.
Sei whale *	0.0008	November.
Sperm whale *	0.0008	September.
Atlantic white-sided dolphin	0.0204	June.
Bottlenose dolphin [a]	0.008	August.
Common dolphin	0.1467	September.
Long-finned pilot whale [b]	0.001	N/A.

TABLE 8—MAXIMUM MEAN MONTHLY MARINE MAMMAL DENSITY ESTIMATES (ANIMALS PER km^2) CONSIDERING A 10-km BUFFER AROUND THE LIMITED INSTALLATION AREA—Continued

Species	Maximum mean density	Maximum density month
Risso's dolphin	0.0013	December.
Harbor porpoise	0.0713	December.
Seals (gray and harbor) [c]	0.1745	May.

Note: * denotes species listed under the ESA.
[a] Density estimate represents the Northwestern Atlantic offshore stock of bottlenose dolphins.
[b] Only annual densities were available for the pilot whale guild.
[c] Gray and harbor seals represented as a guild.

For some species, PSO survey and construction data for SNE (ESS Group, 2016; Vineyard Wind, 2018, 2019, 2023a–f) and mean group size data compiled from the Atlantic Marine Assessment Program for Protected Species (AMAPPS) (Palka *et al.,* 2017, 2021) indicate that the density-based exposure estimates may be insufficient to account for the number of individuals of a species that may be encountered during the planned activities. Hence, consideration of local PSO and AMAPPS data is required to ensure the potential for take is adequately assessed.

In cases where the density-based Level B harassment exposure estimate for a species was less than the mean group size-based exposure estimate, the take request was increased to the mean group size (in some cases multiple groups were assumed) and rounded to the nearest integer (table 9). For all cetaceans, with the exception of NARWs, Vineyard Wind used the mean of the spring, summer, and fall AMAPPS group sizes for each species for the RI/MA WEA as shown in tables 2–2, 2–3, and 2–4 in Palka *et al.* (2021) appendix III. These seasons were selected as they would represent the time period in which pile driving activities would take place. Mean group sizes for cetacean species derived from RI/WEA AMAPPS data is shown below in table 9. However, NARW seasonal group sizes for the RI/MA WEA were not available through the AMAPPS dataset (Palka *et al.,* 2021). Vineyard Wind calculated mean group size for NARWs using data from the northeast (NE) shipboard surveys as provided in table 6–5 of Palka *et al.* (2021). Vineyard Wind calculated mean group size by dividing the number of individual right whales sighted (4) by the number of right whale groups (2) (Palka *et al.,* 2021). The NE shipboard surveys were conducted during summer (June 1 through August 31) and fall (September 1 through November 30) seasons (Palka *et al.,* 2021).

For seals, mean group size data was also not available for the RI/MA WEA through AMAPPS (Palka *et al.,* 2021). Vineyard Wind used 2010–2013 AMAPPS NE shipboard and aerial survey at-sea seal sightings for gray and harbor seals, as well as unidentified seal sightings from spring, summer, and fall to calculate mean group size for gray and harbor seals (table 19–1, Palka *et al.,* 2017). To calculate mean group size for seals, Vineyard Wind divided the total number of animals sighted by the total number of sightings. As the majority of the sightings were not identified to species, Vineyard Wind calculated a single group size for all seal species (table 9).

Additional detail regarding the density and occurrence as well as the assumptions and methodology used to estimate take is included below and in section 6.2 of the ITA application. Mean group sizes used in take estimates, where applicable, for all activities are provided in table 9.

TABLE 9—MEAN MARINE MAMMAL GROUP SIZES USED IN TAKE ESTIMATE CALCULATIONS

Species	Mean group size	Source
NARW *	2	Table 6–5 of Palka *et al.,* 2021.
Fin whale *	1.2	Palka *et al.,* 2021.
Humpback whale	1.2	Palka *et al.,* 2021.
Minke whale	1.4	Palka *et al.,* 2021.
Sei whale *	1	Palka *et al.,* 2021.
Sperm whale *	2	Palka *et al.,* 2021.
Atlantic white-sided dolphin	21.7	Palka *et al.,* 2021.
Bottlenose dolphin	11.7	Palka *et al.,* 2021.
Common dolphin	30.8	Palka *et al.,* 2021.
Long-finned pilot whale	12.3	Palka *et al.,* 2021.
Risso's dolphin	1.8	Palka *et al.,* 2021.
Harbor porpoise	2.9	Palka *et al.,* 2021.
Seals (gray and harbor)	1.4	Table 19–1 of Palka *et al.,* 2017.

Note: * denotes species listed under the ESA.

Vineyard Wind also looked at PSO survey data (June through October 2023) in the LIA collected during Vineyard Wind I construction activities and calculated a daily sighting rate for species to compare with density-based take estimates and average group size estimates from AMAPPS (table 9). The number of animals of each species sighted from all survey vessels with active PSOs was divided by the sum of all PSO monitoring days (77 days) to calculate the mean number of animals of each species sighted (see table 11 in the ITA application). However, for each species, the PSO data-based exposure estimate was less than the density-based exposure estimate (see table 14 in the ITA application) and, therefore, density-based exposure estimates were not adjusted according to PSO data-based exposure estimates.

Here we present the amount of take requested by Vineyard Wind and proposed to be authorized. To estimate take, Vineyard Wind use the pile installation construction schedule

shown in table 6, assuming 15 total days of monopile installation. NMFS has reviewed these methods to estimate take and agrees with this approach. The proposed take numbers in table 11, appropriately consider SFV measurements collected in 2023 and represent the maximum amount of take that is reasonably expected to occur.

TABLE 10—MODELED LEVEL A HARASSMENT AND LEVEL B HARASSMENT ACOUSTIC EXPOSURE ESTIMATES

Species	Density-based exposure estimate	
	Level A harassment	Level B harassment
NARW * [a]	0.503	6.6
Fin whale *	0.598	5.5
Humpback whale	1.11	3.4
Minke whale	0.372	27.7
Sei whale *	0.144	1.2
Sperm whale *	0	1.2
Atlantic white-sided dolphin	0	31.4
Bottlenose dolphin	0	12.3
Common dolphin	0	226
Long-finned pilot whale	0	1.5
Risso's dolphin	0	2
Harbor porpoise	2.758	109.8
Gray Seal	0	240.8
Harbor seal	0.028	28.2

Note: * denotes species listed under the ESA.
[a] Although modeling shows a very low but non-zero exposure estimate for take by Level A harassment, mitigation measures will be applied to ensure there is no take by Level A harassment of this species.

TABLE 11—PROPOSED AUTHORIZED TAKES

[by Level A harassment and Level B harassment]

Species	NMFS stock abundance	Proposed take by Level A harassment	Proposed take by Level B harassment	Total proposed take	Percent of stock abundance
NARW * [a]	338	0	7	7	2.07
Fin whale *	6,802	1	6	7	0.1
Humpback whale	1,396	2	4	6	0.43
Minke whale	21,968	1	28	29	0.13
Sei whale *	6,292	1	2	3	0.05
Sperm whale *	4,349	0	2	2	0.05
Atlantic white-sided dolphin	93,233	0	32	32	0.03
Bottlenose dolphin	62,851	0	13	13	0.02
Common dolphin [b c]	172,974	0	462	462	0.27
Long-finned pilot whale [b]	39,215	0	13	13	0.03
Risso's dolphin	35,215	0	2	2	0.001
Harbor porpoise	95,543	3	110	113	0.19
Gray Seal	27,300	0	241	241	0.88
Harbor seal	61,336	1	29	30	0.05

Note: * denotes species listed under the ESA.
[a] Although modeling shows a very low but non-zero exposure estimate for take by Level A harassment, mitigation measures will be applied to ensure there is no take by Level A harassment of this species.
[b] Proposed take by Level B harassment adjusted according to mean group size.
[c] Proposed take by Level B harassment is based upon the assumption that one group of common dolphins (30.8 dolphins; see table 9) would be encountered per each of the 15 days of pile driving.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to effect the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

The mitigation strategies described below are consistent with those required and successfully implemented under previous incidental take authorizations issued in association with in-water construction activities (*e.g.,* soft-start, establishing shutdown zones). Additional measures have also been incorporated to account for the fact that the proposed construction activities would occur offshore. In addition, several measures proposed for this IHA (*i.e.,* seasonal restrictions, vessel strike avoidance, and clearance and shutdown zones) are more rigorous than measures previously incorporated into the 2023 IHA.

Generally speaking, the mitigation measures considered and proposed to be required here fall into three categories: (1) temporal (seasonal and daily) work restrictions, (2) real-time measures (shutdown, clearance, and vessel strike avoidance), and (3) noise attenuation/reduction measures. Seasonal work restrictions are designed to avoid or minimize operations when marine mammals are concentrated or engaged in behaviors that make them more susceptible or make impacts more likely, in order to reduce both the number and severity of potential takes, and are effective in reducing both chronic (longer-term) and acute effects. Real-time measures, such as implementation of shutdown and clearance zones, as well as vessel strike avoidance measures, are intended to reduce the probability or severity of harassment by taking steps in real time once a higher-risk scenario is identified (*e.g.,* once animals are detected within an impact zone). Noise attenuation measures, such as bubble curtains, are intended to reduce the noise at the source, which reduces both acute impacts, as well as the contribution to aggregate and cumulative noise that may result in longer-term chronic impacts. Below, we also describe the required training, coordination, and vessel strike avoidance measures that apply to foundation installation and vessel use.

Training and Coordination

NMFS requires all Vineyard Wind's employees and contractors conducting activities on the water, including, but not limited to, all vessel captains and crew, to be trained in marine mammal detection and identification, communication protocols, and all required measures to minimize impacts on marine mammals and support Vineyard Wind's compliance with the IHA, if issued. Additionally, all relevant personnel and the marine mammal species monitoring team(s) are required to participate in joint, onboard briefings prior to the beginning of project activities. The briefing must be repeated whenever new relevant personnel (*e.g.,* new PSOs, construction contractors, relevant crew) join the project before work commences. During this training, Vineyard Wind is required to instruct all project personnel regarding the authority of the marine mammal monitoring team(s). For example, pile driving personnel are required to immediately comply with any call for a delay or shut down by the Lead PSO. Any disagreement between the Lead PSO and the project personnel must only be discussed after delay or shutdown has occurred. In particular, all captains and vessel crew must be trained in marine mammal detection and vessel strike avoidance measures to ensure marine mammals are not struck by any project or project-related vessel.

Prior to the start of in-water construction activities, Vineyard Wind would conduct training for construction and vessel personnel and the marine mammal monitoring team (PSO and PAM operators) to explain responsibilities, communication procedures, marine mammal detection and identification, mitigation, monitoring, and reporting requirements, safety and operational procedures, and authorities of the marine mammal monitoring team(s). A description of the training program must be provided to NMFS at least 60 days prior to the initial training before in-water activities begin. Vineyard Wind would provide confirmation of all required training documented on a training course log sheet and reported to NMFS OPR prior to initiating project activities.

NARW Awareness Monitoring

Vineyard Wind would be required to use available sources of information on NARW presence, including daily monitoring of the Right Whale Sightings Advisory System, U.S. Coast Guard very high-frequency (VHF) Channel 16, WhaleAlert, and the PAM system throughout each day to receive notifications of any Slow Zones (*i.e.,* Dynamic management areas (DMAs) and/or acoustically-triggered slow zones) to provide situational awareness for vessel operators, PSOs, and PAM operators. The marine mammal monitoring team must monitor these systems at least every 4 hours. Maintaining daily awareness and coordination affords increased protection of NARWs by understanding NARW presence in the area through ongoing visual and passive acoustic monitoring efforts and opportunities (outside of Vineyard Wind's efforts), and allows for planning of construction activities, when practicable, to minimize potential impacts on NARWs.

Vessel Strike Avoidance Measures

This proposed IHA contains numerous vessel strike avoidance measures that reduce the risk that a vessel and marine mammal could collide. While the likelihood of a vessel strike is generally low, they are one of the most common ways that marine mammals are seriously injured or killed by human activities. Therefore, enhanced mitigation and monitoring measures are required to avoid vessel strikes, to the extent practicable. While many of these measures are proactive, intending to avoid the heavy use of vessels during times when marine mammals of particular concern may be in the area, several are reactive and occur when a project personnel sights a marine mammal. Vineyard Wind would be required to comply with these measures except under circumstances when doing so would create an imminent and serious threat to a person or vessel or to the extent that a vessel is unable to maneuver and, because of the inability to maneuver, the vessel cannot comply.

While underway, Vineyard Wind's personnel would be required to monitor for and maintain a minimum separation distance from marine mammals and operate vessels in a manner that reduces the potential for vessel strike. Regardless of the vessel's size or speed, all vessel operators, crews, and dedicated visual observers (*i.e.,* PSO or trained crew member) must maintain a vigilant watch for all marine mammals and slow down, stop their vessel, or alter course (as appropriate) to avoid striking any marine mammal. The dedicated visual observer, required on all transiting vessels and equipped with suitable monitoring technology (*e.g.,* binoculars, night vision devices), must be located at an appropriate vantage point for ensuring vessels are maintaining required vessel separation distances from marine mammals (*e.g.,* 500 m from NARWs).

All of the project-related vessels would be required to comply with existing NMFS vessel speed restrictions for NARWs, and additional speed and approach restrictions measures within this IHA. All vessels must reduce speed to 10 kn or less when traveling in a DMA, Slow Zone or when a NARW is observed or acoustically detected. Reducing vessel speed is one of the most effective, feasible options available

to reduce the likelihood of and effects from a vessel strike. Numerous studies have indicated that slowing the speed of vessels reduces the risk of lethal vessel collisions, particularly in areas where right whales are abundant and vessel traffic is common and otherwise traveling at high speeds (Vanderlaan and Taggart, 2007; Conn and Silber, 2013; Van der Hoop *et al.,* 2014; Martin *et al.,* 2015; Crum *et al.,* 2019).

When NMFS vessel speed restrictions are not in effect and a vessel is traveling at greater than 10 kn (18.5 km/hr), in addition to the required dedicated visual observer, Vineyard Wind would be required to monitor the crew transfer vessel transit corridor (the path crew transfer vessels take from port to any work area) in real-time with PAM prior to and during transits.

All project vessels, regardless of size, must maintain the following minimum separation zones: 500 m from NARWs; 100 m from sperm whales and non-NARW baleen whales; and 50 m from all delphinid cetaceans and pinnipeds (an exception is made for those species that approach the vessel such as bow-riding dolphins) (table 12). All reasonable steps must be taken to not violate minimum separation distances. If any of these species are sighted within their respective minimum separation zone, the underway vessel must turn away from the animal and shift its engine to neutral (if safe to do so) and the engines must not be engaged until the animal(s) have been observed to be outside of the vessel's path and beyond the respective minimum separation zone. If a NARW is observed at any distance by any project personnel or acoustically detected, project vessels must reduce speeds to 10 kn and turn away from the animal. Additionally, in the event that any project-related vessel, regardless of size, observes any large whale (other than a NARW) within 500 m of an underway vessel, the vessel is required to immediately reduce speeds to 10 kn or less and turn away from the animal.

TABLE 12—VESSEL STRIKE AVOIDANCE SEPARATION ZONES

Marine mammal species	Vessel separation zone (m)
NARW	500
Other ESA-listed species and non-NARW large whales	100
Other marine mammals [a]	50

[a] With the exception of seals and delphinid(s) from the genera *Delphinus, Lagenorhynchus, Stenella,* or *Tursiops,* as described below.

Any marine mammal observed by project personnel must be immediately communicated to any on-duty PSOs, PAM operator(s), and all vessel captains. Any NARW or large whale observation or acoustic detection by PSOs or PAM operators must be conveyed to all vessel captains. All vessels would be equipped with an AIS and Vineyard Wind must report all Maritime Mobile Service Identity (MMSI) numbers to NMFS OPR prior to initiating in-water activities. Vineyard Wind has submitted an updated NMFS-approved NARW Vessel Strike Avoidance Plan, which NMFS is reviewing for alignment with the measures proposed herein.

Given the extensive vessel strike avoidance measures coupled with the limited amount of work associated with the project, NMFS has determined that Vineyard Wind's compliance with these proposed measures would reduce the likelihood of vessel strike to discountable levels.

Seasonal and Daily Restrictions

Temporal restrictions in places where marine mammals are concentrated, engaged in biologically important behaviors, and/or present in sensitive life stages are effective measures for reducing the magnitude and severity of human impacts. The temporal restrictions proposed here are built around NARW protection. Based upon the best scientific information available (Roberts *et al.,* 2023), the highest densities of NARWs in the specified geographic region are expected during the months of January through May, with an increase in density starting in December. However, NARWs may be present in the specified geographic region throughout the year.

NMFS is proposing to require seasonal work restrictions to minimize risk of noise exposure to the NARWs incidental to pile driving activities to the extent practicable. These seasonal work restrictions are expected to reduce the number of takes of NARWs and further reduce vessel strike risk. These seasonal restrictions also afford protection to other marine mammals that are known to use the LIA with greater frequency during winter months, including other baleen whales. As described previously, no impact pile driving activities may occur January 1 through May 31, and pile driving in December must be avoided to the maximum extent practicable and only if enhanced monitoring is undertaken and NMFS approves.

Vineyard Wind proposed to install no more than one pile per day and only initiate impact pile driving during daylight hours. Vineyard Wind would not be able to initiate pile driving later than 1.5 hours after civil sunset or continue pile driving after or 1 hour before civil sunrise. However, if Vineyard Wind determines that they must initiate pile driving after the aforementioned time frame, they must submit a sufficient nighttime pile driving plan for NMFS review and approval to do so. A sufficient nighttime pile driving plan would demonstrate that proposed detection systems would be capable of detecting marine mammals, particularly large whales, at distances necessary to ensure mitigation measures are effective.

Noise Attenuation Systems

Vineyard Wind would be required to employ noise abatement systems (NAS), also known as noise attenuation systems, during all foundation installation activities to reduce the sound pressure levels that are transmitted through the water in an effort to reduce acoustic ranges to the Level A harassment and Level B harassment acoustic thresholds and minimize, to the extent practicable, any acoustic impacts resulting from these activities. Vineyard Wind proposes and NMFS is proposing to require Vineyard Wind to use a double bubble curtain (DBBC) and Hydro Sound damper (HSD) in addition to an enhanced big bubble curtain (BBC) maintenance schedule. The refined NAS design (DBBC + HSD + enhanced bubble curtain (BC) maintenance schedule) used during the 2023 construction activities would be used on the 15 remaining piles to minimize noise levels. A single bubble curtain, alone or in combination with another NAS device, may not be used for pile driving as received SFV data reveals this approach is unlikely to attenuate sound sufficiently to be

consistent with the target sound reduction of 6 dB, in which the expected ranges to the Level A harassment and Level B harassment isopleths are based upon.

Two categories of NAS exist: primary and secondary. A primary NAS would be used to reduce the level of noise produced by foundation installation activities at the source, typically through adjustments to the equipment (*e.g.,* hammer strike parameters). Primary NAS are still evolving and will be considered for use during mitigation efforts when the NAS has been demonstrated as effective in commercial projects. However, as primary NAS are not fully effective at eliminating noise, a secondary NAS would be employed. The secondary NAS is a device or group of devices that would reduce noise as it is transmitted through the water away from the pile, typically through a physical barrier that would reflect or absorb sound waves and therefore reduce the distance the higher energy sound propagates through the water column. Together, these systems must reduce noise levels to those not exceeding expected ranges to Level A harassment and Level B harassment isopleths corresponding to those modeled assuming 6-dB sound attenuation, pending results of SFV (see *Sound Field Verification* section below).

Noise abatement systems, such as bubble curtains, are used to decrease the sound levels radiated from a source. Bubbles create a local impedance change that acts as a barrier to sound transmission. The size of the bubbles determines their effective frequency band, with larger bubbles needed for lower frequencies. There are a variety of bubble curtain systems, confined or unconfined bubbles, and some with encapsulated bubbles or panels. Attenuation levels also vary by type of system, frequency band, and location. Small bubble curtains have been measured to reduce sound levels, but effective attenuation is highly dependent on depth of water, current, and configuration and operation of the curtain (Austin *et al.,* 2016; Koschinski and Lüdemann, 2013). Bubble curtains vary in terms of the sizes of the bubbles; those with larger bubbles tend to perform a bit better and more reliably, particularly when deployed with two separate rings (Bellmann, 2014; Koschinski and Lüdemann, 2013; Nehls *et al.,* 2016). Encapsulated bubble systems (*i.e.,* HSDs) can be effective within their targeted frequency ranges (*e.g.,* 100–800 Hz) and when used in conjunction with a bubble curtain appear to create the greatest attenuation. The literature presents a wide array of observed attenuation results for bubble curtains. The variability in attenuation levels is the result of variation in design as well as differences in site conditions and difficulty in properly installing and operating in-water attenuation devices.

For example, Dähne *et al.* (2017) found that single bubble curtains that reduce sound levels by 7 to 10 dB reduced the overall sound level by approximately 12 dB when combined as a double bubble curtain for 6-m steel monopiles in the North Sea. During installation of monopiles (consisting of approximately 8-m in diameter) for more than 150 WTGs in comparable water depths (>25 m) and conditions in Europe indicate that attenuation of 10 dB is readily achieved (Bellmann, 2019; Bellmann *et al.,* 2020) using single BBCs for noise attenuation. When a DBBC is used (noting a single BC is not allowed), Vineyard Wind would be required to maintain numerous operational performance standards, including the enhanced BBC maintenance protocol (Vineyard Wind Enhanced BBC Technical Memo, 2023). These standards are defined in the proposed IHA and include, but are not limited to, a requirement that construction contractors train personnel in the proposed balancing of airflow to the bubble ring; and a requirement that Vineyard Wind submit a performance test and maintenance report to NMFS within 72 hours following the performance test. Corrections to the attenuation device to meet regulatory requirements must occur prior to use during foundation installation activities. In addition, a full maintenance check (*e.g.,* manually clearing holes) must occur prior to each pile being installed.

The HSD system Vineyard Wind proposes to use would be employed, in coordination with the DBBC, as a near-field attenuation device close to the monopiles (Küsel *et al.,* 2024). Vineyard Wind has also proposed to follow a DBBC enhanced maintenance protocol, which was used during the 2023 Vineyard Wind pile installation activities. The DBBC enhanced maintenance protocol includes an adjustment from typical bubble curtain operations to drill hoses after every deployment to maximize performance in siltier sediments which are present in the Lease Area. The DBBC enhanced maintenance protocol also includes DBBC hose inspection and clearance, pressure testing of DBBC hoses, visual inspection of DBBC performance, and minimizing disturbance of the DBBC hoses on the seafloor.

Should SFV identify that distances to NMFS harassment isopleths are louder than expected, Vineyard Wind would be required to adjust the NAS, or conduct other measures to reduce noise levels, such that distances to thresholds are not exceeded.

Clearance and Shutdown Zones

NMFS is proposing to require the establishment of both clearance and shutdown zones during impact pile driving. The purpose of ''clearance'' of a particular zone is to minimize potential instances of auditory injury and more severe behavioral disturbances by delaying the commencement of an activity if marine mammals are near the activity. The purpose of a ''shutdown'' is to prevent a specific acute impact, such as auditory injury or severe behavioral disturbance of sensitive species, by halting the activity. Due to the increased density of NARWs during the months of November and December, more stringent clearance and shutdown mitigation measures are proposed for these months.

All relevant clearance and shutdown zones during project activities would be monitored by NMFS-approved PSOs and PAM operators. PAM would be conducted at least 24 hours in advance of any pile driving activities. At least one PAM operator would review data from at least 24 hours prior to foundation installation (to increase situational awareness) and actively monitor hydrophones for 60 minutes prior to commencement of these activities. Any sighting or acoustic detection of a NARW would trigger a delay to commencing pile driving and shutdown.

Prior to the start of pile driving activities, Vineyard Wind would be required to ensure designated areas (*i.e.,* clearance zones, table 13) are clear of marine mammals before commencing activities to minimize the potential for and degree of harassment. Three on-duty PSOs would monitor from the pile driving support vessel and two PSO support vessels, each with three PSOs on board, before (60 minutes), during, and after (30 minutes) all pile driving. PSOs must visually monitor clearance zones for marine mammals for a minimum of 60 minutes, where the zone must be confirmed free of marine mammals at least 30 minutes directly prior to commencing these activities. The minimum visibility zone, defined as the area over which PSOs must be able to visually detect marine mammals, would extend 4,000 m for monopile installation from the pile being driven (table 13), and must be visible for 60 minutes. The minimum visibility zone corresponds to the modeled Level A harassment distance for low-frequency cetaceans plus twenty percent, and

rounded up to the nearest 0.5 km. The minimum visibility zone must be visually cleared of marine mammals. If this zone is obscured to the degree that effective monitoring cannot occur, pile driving must be delayed. Minimum visibility zone and clearance zones are defined and provided in table 13 for all species.

From December 1 to 31, a vessel-based survey would be used to confirm the clearance zone (10 km PAM clearance zone (6.2 mi); table 13) is clear of NARWs prior to pile driving. The survey would be supported by a team of nine PSOs coordinating visual monitoring across two PSO support vessels and the pile driving platform. The two PSO support vessels, each with three active on-duty PSOs, would be positioned at the same distance on either side of the pile driving vessel. Each PSO support vessel would transit along a steady course along parallel track lines in opposite directions. Each transect line would be surveyed at a similar speed, not to exceed 10 kn, and would last for approximately 30 minutes to 1 hour. If a NARW is sighted at any distance during the vessel-based survey, pile driving would be delayed until the following day unless an additional vessel-based survey with additional transects are conducted to determine the clearance zone is clear of NARWs. Further details on PSO support vessel monitoring efforts are described in the Vineyard Wind application section 11, table 17.

Once pile driving activity begins, any marine mammal entering their respective shutdown zone would trigger the activity to cease. In the case of pile driving, the shutdown requirement may be waived if is not practicable due to imminent risk of injury or loss of life to an individual or risk of damage to a vessel that creates risk of injury or loss of life for individuals, or if the lead engineer determines there is pile refusal or pile instability.

In situations when shutdown is called for, but Vineyard Wind determines shutdown is not practicable due to aforementioned emergency reasons, reduced hammer energy must be implemented when the lead engineer determines it is practicable. Specifically, pile refusal or pile instability could result in the inability to shut down pile driving immediately. Pile refusal occurs when the pile driving sensors indicate the pile is approaching refusal, and a shut-down would lead to a stuck pile which then poses an imminent risk of injury or loss of life to an individual, or risk of damage to a vessel that creates risk for individuals. Pile instability occurs when the pile is unstable and unable to stay standing if the piling vessel were to ''let go.'' During these periods of instability, the lead engineer may determine a shut-down is not feasible because the shut-down combined with impending weather conditions may require the piling vessel to ''let go'' which then poses an imminent risk of injury or loss of life to an individual, or risk of damage to a vessel that creates risk for individuals. Vineyard Wind must document and report to NMFS all cases where the emergency exemption is taken.

After shutdown, impact pile driving may be reinitiated once all clearance zones are clear of marine mammals for the minimum species-specific periods, or, if required to maintain pile stability, impact pile driving may be reinitiated but must be used to maintain stability. From June 1 to October 31, if pile driving has been shut down due to the presence of a NARW, pile driving must not restart until the NARW has not been visually or acoustically detected for 30 minutes. Upon re-starting pile driving, soft-start protocols must be followed if pile driving has ceased for 30 minutes or longer. From November 1 to December 31, if pile driving has been shut down or delayed due to the presence of three or more NARWs, pile driving will be postponed until the next day. Shutdown zones vary by species and are shown in table 13 below.

TABLE 13—MINIMUM VISIBILITY, CLEARANCE, SHUTDOWN, AND LEVEL B HARASSMENT ZONES, IN METERS (m), DURING IMPACT PILE DRIVING

Monitoring zones	NARWs [a]	Other mysticetes/ sperm whales (m) [b]	Pilot whales, harbor porpoises, and delphinids (m) [b]	Pinnipeds (m) [b]
Minimum Visibility Zone [c]	4,000			
Visual Clearance Zone	Any distance from PSOs	500	160	160
PAM Clearance Zone	10,000	500	160	160
Visual Shutdown Zone	Any distance	500	160	160
PAM Monitoring Zone [d]	10,000	500	160	160
Distance to Level B Harassment Threshold	5,720			

[a] From December 1 to December 31, vessel based surveys using two PSO support vessels would confirm that the 10-km (6.2-mi) PAM clearance zone is clear of NARWs. If three or more NARWs are sighted in November or December, pile driving will be delayed for 24 hours.

[b] Pile driving may commence when either the marine mammal has voluntarily left the respective clearance zone and has been visually confirmed beyond that clearance zone, or when 30 minutes (NARWs (June-October), other non-NARW mysticetes, sperm whales, pilot whales, Risso's dolphins) or 15 minutes (all other delphinids and pinnipeds)have elapsed without re-detection.

[c] Minimum visibility zone is the minimum distance that must be visible prior to initiating pile driving, as determined by the lead PSO. The minimum visibility zone corresponds to the Level A harassment distance for low-frequency cetaceans plus twenty percent, and rounded up to the nearest 0.5 km

[d] The PAM system must be capable of detecting NARWs at 10 km during pile driving. The system should also be designed to detect other marine mammals to the maximum extent practicable; however, it is not required these other species be detected out to 10 km given higher frequency calls and echolocation clicks are not typically detectable at large distances.

For any other in-water construction heavy machinery activities (*e.g.,* trenching, cable laying, *etc.*), if a marine mammal is on a path towards or comes within 10 m (32.8 ft) of equipment, Vineyard Wind would be required to delay or cease operations until the marine mammal has moved more than 10 m on a path away from the activity to avoid direct interaction with equipment.

Soft-start

The use of a soft-start procedure is believed to provide additional protection to marine mammals by warning them or providing them with a chance to leave the area prior to the

hammer operating at full capacity. Soft-start typically involves initiating hammer operation at a reduced energy level (relative to full operating capacity) followed by a waiting period. Vineyard Wind would be required to utilize a soft-start protocol for impact pile driving of monopiles by performing four to six single hammer strikes at less than 40 percent of the maximum hammer energy followed by at least a 1-minute delay before the subsequent hammer strikes. This process shall be conducted at least tjree times (*e.g.,* four to six single strikes, delay, four to six single strikes, delay, four to six single strikes, delay) for a minimum of 20 minutes. NMFS notes that it is difficult to specify a reduction in energy for any given hammer because of variation across drivers and installation conditions. Vineyard Wind will reduce energy based on consideration of site-specific soil properties and other relevant operational considerations.

Soft start would be required at the beginning of each day's activity and at any time following a cessation of activity of 30 minutes or longer. Prior to soft-start, the operator must receive confirmation from the PSO that the clearance zone is clear of any marine mammals.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. NMFS' MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorization must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Separately, monitoring is also regularly used to support mitigation implementation, which is referred to as mitigation monitoring, and monitoring plans typically include measures that both support mitigation implementation and increase our understanding of the impacts of the activity on marine mammals.

Protected Species Observer and PAM Operator Requirements

PSOs are trained professionals who are tasked with visual monitoring for marine mammals during pile driving activities. The primary purpose of a PSO is to carry out the monitoring, collect data, and, when appropriate, call for the implementation of mitigation measures. Visual monitoring by NMFS-approved PSOs would be conducted at a minimum of 60 minutes before, during, and 30 minutes after all proposed impact pile driving activities. In addition to visual observations, NMFS would require Vineyard Wind to conduct PAM using NMFS-approved PAM operators during impact pile driving and vessel transit. PAM would also be conducted for 24 hours in advance and during impact pile driving activities. Visual observations and acoustic detections would be used to support the mitigation measures (*e.g.,* clearance zones). To increase understanding of the impacts of the activity on marine mammals, PSOs must record all incidents of marine mammal occurrence at any distance from the piling locations. PSOs would document all behaviors and behavioral changes, in concert with distance from an acoustic source.

NMFS proposes to require PAM conducted by NMFS-approved PAM operators, following a standardized measurement, processing methods, reporting metrics, and metadata standards for offshore wind. PAM alongside visual data collection is valuable to provide the most accurate record of species presence as possible, and these two monitoring methods are well understood to provide best results when combined together (*e.g.,* Barlow and Taylor, 2005; Clark *et al.,* 2010; Gerrodette *et al.,* 2011; Van Parijs *et al.,* 2021). Acoustic monitoring (in addition to visual monitoring) increases the likelihood of detecting marine mammals within the shutdown and clearance zones of project activities, which when applied in combination with required shutdowns helps to further reduce the risk of marine mammals being exposed to sound levels that could otherwise result in acoustic injury or more intense behavioral harassment.

The exact configuration and number of PAM systems depends on the size of the zone(s) being monitored, the amount of noise expected in the area, and the characteristics of the signals being monitored. More closely spaced hydrophones would allow for more directionality, and perhaps, range to the vocalizing marine mammals; although, this approach would add additional costs and greater levels of complexity to the project. Larger baleen cetacean species (*i.e.,* mysticetes), which produce loud and lower-frequency vocalizations, may be able to be heard with fewer hydrophones spaced at greater distances. However, smaller cetaceans (such as mid-frequency delphinids or odontocetes) may necessitate more hydrophones and to be spaced closer together given the shorter range of the shorter, mid-frequency acoustic signals (*e.g.,* whistles and echolocation clicks). The configuration for collecting the required marine mammal data will be based upon the acoustic data acquisition methods used during the 2023 Vineyard Wind construction campaign (Küsel *et al.,* 2024).

NMFS does not formally administer any PSO or PAM operator training program or endorse specific providers but would approve PSOs and PAM

operators that have successfully completed courses that meet the curriculum and trainer requirements. All PSOs and PAM operators must have successfully attained a bachelor's degree from an accredited college or university with a major in one of the natural sciences, a minimum of 30 semester hours or equivalent in the biological sciences, and at least one undergraduate course in math or statistics. The educational requirements may be waived if the PSO or PAM operator has acquired the relevant skills through alternate experience. Requests for such a waiver shall be submitted to NMFS and must include written justification. Alternate experience that may be considered includes, but is not limited to: (1) secondary education and/or experience comparable to PSO and/or PAM operator duties; (2) previous work experience conducting academic, commercial, or government-sponsored marine mammal surveys; and (3) previous work experience as a PSO/PAM operator (PSOs/PAM operators must be in good standing and demonstrate good performance of PSO/PAM operator duties). All PSOs and PAM operators must have successfully completed a relevant training course within the last 5 years, including obtaining a certificate of course completion that would be submitted to NMFS.

For prospective PSOs and PAM operators not previously approved, or for PSOs and PAM operators whose approval is not current, NMFS must review and approve PSO and PAM operator qualifications. Vineyard Wind would be required to submit PSO and PAM operator resumes for approval at least 60 days prior to PSO and PAM operator use. Resumes must include information related to relevant education, experience, and training, including dates, duration, location, and description of prior PSO and/or PAM experience, and be accompanied by relevant documentation of successful completion of necessary training. Should Vineyard Wind require additional PSOs or PAM operators throughout the project, Vineyard Wind must submit a subsequent list of pre-approved PSOs and PAM operators to NMFS at least 15 days prior to planned use of that PSO or PAM operator. PSOs and PAM operators must have previous experience observing marine mammals and must have the ability to work with all required and relevant software and equipment.

PAM operators are responsible for obtaining NMFS approval. To be approved as a PAM operator, the person must meet the following qualifications: The PAM operator must demonstrate that they have prior experience with real-time acoustic detection systems and/or have completed specialized training for operating PAM systems and detecting and identifying Atlantic Ocean marine mammal sounds, in particular, NARW sounds, humpback whale sounds, and how to deconflict them from similar NARW sounds, and other co-occurring species' sounds in the area including sperm whales. The PAM operator must be able to distinguish between whether a marine mammal or other species sound is detected, possibly detected, or not detected, and similar terminology must be used across companies/projects. Where localization of sounds or deriving bearings and distance are possible, the PAM operators need to have demonstrated experience in using this technique. PAM operators must be independent observers (*i.e.,* not construction personnel), and must demonstrate experience with relevant acoustic software and equipment. PAM operators must have the qualifications and relevant experience/training to safely deploy and retrieve equipment and program the software, as necessary. PAM operators must be able to test software and hardware functionality prior to operation, and PAM operators must have evaluated their acoustic detection software using the PAM Atlantic baleen whale annotated data set available at National Centers for Environmental Information (NCEI) and provide evaluation/performance metric. PAM operators must also be able to review and classify acoustic detections in real-time (prioritizing NARWs and noting detection of other cetaceans) during the real-time monitoring periods.

NMFS may approve PSOs and PAM operators as conditional or unconditional. An unconditionally approved PSO or PAM operator is one who has completed training within the last 5 years and attained the necessary experience (*i.e.,* demonstrate experience with monitoring for marine mammals at clearance and shutdown zone sizes similar to those produced during the respective activity). A conditionally approved PSO or PAM operator may be one who has completed training in the last 5 years but has not yet attained the requisite field experience.

Conditionally approved PSOs and PAM operators would be paired with an unconditionally approved PSO (or PAM operator, as appropriate) to ensure that the quality of marine mammal observations and data recording is kept consistent. Additionally, impact pile driving activities would require PSOs and/or PAM operator monitoring to have a lead on duty. The visual PSO field team, in conjunction with the PAM team (*i.e.,* marine mammal monitoring team) would have a lead member (designated as the ''Lead PSO'' or ''Lead PAM operator'') who would be required to meet the unconditional approval standard. Lead PSO or PAM operators must also have a minimum of 90 days in a northwestern Atlantic Ocean offshore environment performing the role (either visual or acoustic), with the conclusion of the most recent relevant experience not more than 18 months previous. A PSO may be trained and/or experienced as both a PSO and PAM operator and may perform either duty, pursuant to scheduling requirements (and vice versa).

PSOs must have visual acuity in both eyes (with correction of vision being permissible) sufficient enough to discern moving targets on the water's surface with the ability to estimate the target size and distance (binocular use is allowable), ability to conduct field observations and collect data according to the assigned protocols, and the ability to communicate orally, by radio, or in-person, with project personnel to provide real-time information on marine mammals observed in the area. All PSOs must be trained in northwestern Atlantic Ocean marine mammal identification and behaviors and must be able to conduct field observations and collect data according to assigned protocols. Additionally, PSOs must have the ability to work with all required and relevant software and equipment necessary during observations.

Vineyard Wind must work with the selected third-party PSO and PAM operator provider to ensure PSOs and PAM operators have all equipment (including backup equipment) needed to adequately perform necessary tasks. For PSOs, this includes, but is not limited to, accurate determination of distance and bearing to observed marine mammals, and to ensure that PSOs are capable of calibrating equipment as necessary for accurate distance estimates and species identification. PSO equipment, at a minimum, shall include:

- At least one thermal (infrared) imaging device suited for the marine environment;
- Reticle binoculars (*e.g.,* 7×50) of appropriate quality (at least one per PSO, plus backups);
- Global positioning units (GPS) (at least one plus backups);
- Digital cameras with a telephoto lens that is at least 300 mm or equivalent on a full-frame single lens reflex (SLR) (at least one plus backups).

The camera or lens should also have an image stabilization system;

- Equipment necessary for accurate measurement of distances to marine mammal;
- Compasses (at least one plus backups);
- Means of communication among vessel crew and PSOs; and,
- Any other tools deemed necessary to adequately and effectively perform PSO tasks.

At least two PSOs on the pile driving vessel must be equipped with functional Big Eye binoculars (*e.g.,* 25 × 150; 2.7 view angle; individual ocular focus; height control), Big Eye binocular would be pedestal mounted on the deck at the best vantage point that provides for optimal sea surface observation and PSO safety. PAM operators must have the appropriate equipment (*i.e.,* a computer station equipped with a data collection software system available wherever they are stationed) and use a NMFS-approved PAM system to conduct monitoring. The equipment specified above may be provided by an individual PSO, the third-party PSO provider, or the operator, but Vineyard Wind is responsible for ensuring PSOs have the proper equipment required to perform the duties specified in the IHA. Reference materials must be available aboard all project vessels for identification of protected species.

PSOs and PAM operators would not be permitted to exceed 4 consecutive watch hours on duty at any time, would have a 2-hour (minimum) break between watches, and would not exceed a combined watch schedule of more than 12 hours in a 24-hour period. If the schedule includes PSOs and PAM operators on-duty for 2-hour shifts, a minimum 1-hour break between watches would be allowed.

The PSOs would be responsible for monitoring the waters surrounding the pile driving site to the farthest extent permitted by sighting conditions, including pre-start clearance and shutdown zones, prior to, during, and following foundation installation activities. Monitoring must be done while free from distractions and in a consistent, systematic, and diligent manner. If PSOs cannot visually monitor the minimum visibility zone of 4 km (2.5 mi) prior to foundation pile driving at all times using the required equipment, pile driving operations must not commence or must shutdown if they are currently active. All PSOs must be located at the best vantage point(s) on any platform, as determined by the Lead PSO, in order to obtain 360-degree visual coverage of the entire clearance and shutdown zones, and as much of the Level B harassment zone as possible. PAM operators may be located on a vessel or remotely on-shore, and must assist PSOs in ensuring full coverage of the clearance and shutdown zones. The PAM operator must monitor to and past the clearance zones for large whales.

All on-duty PSOs must remain in real-time contact with the on-duty PAM operator(s). PAM operators must immediately communicate all acoustic detections of marine mammals to PSOs, including any determination regarding species identification, distance, and bearing (where relevant) relative to the pile being driven and the degree of confidence (*e.g.,* possible, probable detection) in the determination. The PAM operator must inform the Lead PSO(s) on duty of animal detections approaching or within applicable ranges of interest to the activity occurring via the data collection software system (*i.e.,* Mysticetus or similar system) who must be responsible for requesting that the designated crewmember implement the necessary mitigation procedures (*i.e.,* delay). All on-duty PSOs and PAM operator(s) must remain in contact with the on-duty construction personnel responsible for implementing mitigations (*e.g.,* delay to pile driving) to ensure communication on marine mammal observations can easily, quickly, and consistently occur between all on-duty PSOs, PAM operator(s), and on-water Project personnel. It would be the responsibility of the PSO(s) on duty to communicate the presence of marine mammals as well as to communicate the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate.

At least three PSOs (on the pile driving vessel) and one PAM operator would be on-duty and actively monitoring for marine mammals 60 minutes before, during, and 30 minutes after foundation installation in accordance with a NMFS-approved PAM Plan. PAM would also be conducted for at least 24 hours prior to foundation pile driving activities, and the PAM operator must review all detections from the previous 24-hour period prior to pile driving activities to increase situational awareness. Throughout the year (June through December), at least three PSOs would also be on-duty and actively monitoring from PSO support vessels. There would be at least two PSO support vessels with on-duty PSOs during any pile driving activities from June through December.

In addition to monitoring duties, PSOs and PAM operators are responsible for data collection. The data collected by PSO and PAM operators and subsequent analysis provide the necessary information to inform an estimate of the amount of take that occurred during the project, better understand the impacts of the project on marine mammals, address the effectiveness of monitoring and mitigation measures, and to adaptively manage activities and mitigation in the future. Data reported includes information on marine mammal sightings, activity occurring at time of sighting, monitoring conditions, and if mitigative actions were taken.

For all visual monitoring efforts and marine mammal sightings, NMFS proposes that the following information must be collected and reported to NMFS OPR: the date and time that monitored activity begins or ends, the construction activities occurring during each observation period, the watch status (*i.e.,* sighting made by PSO on/off effort, opportunistic, crew, alternate vessel/platform), the PSO who sighted the animal, the time of sighting; the weather parameters (*e.g.,* wind speed, percent cloud cover, visibility), the water conditions (*e.g.,* Beaufort sea state, tide state, water depth); all marine mammal sightings, regardless of distance from the construction activity; species (or lowest possible taxonomic level possible), the pace of the animal(s), the estimated number of animals (minimum/maximum/high/low/best), the estimated number of animals by cohort (*e.g.,* adults, yearlings, juveniles, calves, group composition, *etc.*), the description (*i.e.,* as many distinguishing features as possible of each individual seen, including length, shape, color, pattern, scars or markings, shape and size of dorsal fin, shape of head, and blow characteristics), the description of any marine mammal behavioral observations (*e.g.,* observed behaviors such as feeding or traveling) and observed changes in behavior, including an assessment of behavioral responses thought to have resulted from the specific activity, the animal's closest distance and bearing from the pile being driven and estimated time entered or spent within the Level A harassment and/or Level B harassment zone(s), use of noise attenuation device(s), and specific phase of activity (*e.g.,* soft-start for pile driving, active pile driving, *etc.*), the marine mammal occurrence in Level A harassment or Level B harassment zones, the description of any mitigation-related action implemented, or mitigation-related actions called for but not implemented, in response to the sighting (*e.g.,* delay, shutdown, *etc.*) and time and location of the action, and other human activity in the area.

On May 19, 2023, Vineyard Wind submitted a Pile Driving Monitoring

Plan for the 2023 IHA, including an Alternative Monitoring Plan, which was approved by NMFS. The Plan included details regarding PSO and PAM monitoring protocols and equipment proposed for use. More specifically, the PAM portion of the plan included a description of all proposed PAM equipment, addressed how the proposed passive acoustic monitoring must follow standardized measurement, processing methods, reporting metrics, and metadata standards for offshore wind as described in ''NOAA and BOEM Minimum Recommendations for Use of Passive Acoustic Listening Systems in Offshore Wind Energy Development Monitoring and Mitigation Programs'' (Van Parijs *et al.,* 2021). This plan also identified the efficacy of the technology at detecting marine mammals in the clearance and shutdown zones under all of the various conditions anticipated during construction, including varying weather conditions, sea states, and in consideration of the use of artificial lighting. Vineyard Wind would be required to submit an updated Foundation Installation Pile Driving Marine Mammal Monitoring Plan to NMFS Office of Protected Resources for review, and the Plan must be approved by NMFS prior to the start of foundation pile driving.

Sound Field Verification

Vineyard Wind would be required to conduct thorough SFV measurements during impact pile driving activity associated with the installation of, at minimum, the first monopile foundation and abbreviated SFV measurements during impact installation of the remaining monopiles to demonstrate noise levels are at or below those measured during the 2023 Vineyard Wind construction campaign (Küsel *et al.,* 2024). NMFS recognizes that the SFV data collected in 2023 occurred in warmer weather months and that water temperature can affect the sound speed profile and, thus, propagation rates. Therefore, if impact pile driving takes place in December, thorough SFV measurements must be conducted during impact pile driving activity associated with the installation of, at minimum, the first monopile foundation. Subsequent SFV measurements would also be required should larger piles be installed or if additional piles are driven that are anticipated to produce louder sound fields than those previously measured (*e.g.,* higher hammer energy, greater number of strikes, *etc.*). The measurements and reporting associated with SFV can be found in the IHA. The proposed requirements are extensive to ensure monitoring is conducted appropriately and the reporting frequency is such that Vineyard Wind would be required to make adjustments quickly (*e.g.,* add additional sound attenuation) to ensure marine mammals are not experiencing noise levels above those considered in this analysis. For recommended SFV protocols for impact pile driving, please consult ISO 18406 ''Underwater acoustics—Measurement of radiated underwater sound from percussive pile driving'' (2017). Vineyard Wind would be required to submit an updated SFV plan to NMFS Office of Protected Resources for review, and the Plan must be approved by NMFS prior to the start of foundation pile driving.

For any pile driving activities, they would also be required to submit interim and final SFV data results to NMFS and make corrections to the noise attenuation systems in the case that any SFV measurements demonstrate noise levels are above those expected assuming 6 dB of attenuation. These frequent and immediate reports would allow NMFS to better understand the sound fields to which marine mammals are being exposed and require immediate corrective action should they be misaligned with anticipated noise levels within our analysis.

Reporting

Prior to any construction activities occurring, Vineyard Wind would provide a report to NMFS OPR that demonstrates that all Vineyard Wind personnel, which includes the vessel crews, vessel captains, PSOs, and PAM operators have completed all required training. NMFS would require standardized and frequent reporting from Vineyard Wind during the active period of the IHA. All data collected relating to the Project would be recorded using industry-standard software (*e.g.,* Mysticetus or a similar software) installed on field laptops and/or tablets. Vineyard Wind would be required to submit weekly, monthly, annual, and situational reports. Vineyard Wind must review SFV results within 24 hours to determine whether measurements exceeded modeled (Level A harassment) and expected (Level B harassment) thresholds.

Vineyard Wind must provide the initial results of the SFV measurements to NMFS OPR in an interim report after each foundation installation event as soon as they are available and prior to a subsequent foundation installation, but no later than 48 hours after each completed foundation installation event. The report must include, at minimum: hammer energies/schedule used during pile driving, including the total number of strikes and the maximum hammer energy, peak sound pressure level (SPL_{pk}), root-mean-square sound pressure level that contains 90 percent of the acoustic energy (SPL_{rms}), and sound exposure level (SEL, in single strike for pile driving, SEL_{ss}), for each hydrophone, including at least the maximum, arithmetic mean, minimum, median (L50) and L5 (95 percent exceedance) statistics for each metric; estimated marine mammal Level A harassment and Level B harassment isopleths, calculated using the maximum-over-depth L5 (95 percent exceedance level, maximum of both hydrophones) of the associated sound metric, comparison of 2023 measured results against the measured marine mammal Level A harassment and Level B harassment acoustic isopleths, estimated transmission loss coefficients, pile identifier name, location of the pile and each hydrophone array in latitude/longitude, depths of each hydrophone, one-third-octave band single strike SEL spectra, if filtering is applied, full filter characteristics, and hydrophone specifications including the type, model, and sensitivity. Vineyard Wind would also be required to report any immediate observations which are suspected to have a significant impact on the results including but not limited to: observed noise mitigation system issues, obstructions along the measurement transect, and technical issues with hydrophones or recording devices. If any in-situ calibration checks for hydrophones reveal a calibration drift greater than 0.75 dB, pistonphone calibration checks are inconclusive, or calibration checks are otherwise not effectively performed, Vineyard Wind would be required to indicate full details of the calibration procedure, results, and any associated issues in the 48-hour interim reports.

Vineyard Wind must review abbreviated SFV results for each pile within 24 hours of completion of the foundation installation (inclusive of pile driving and any drilling), and, assuming measured levels at 750 m did not exceed the thresholds defined during thorough SFV, does not need to take any additional action. Results of abbreviated SFV must be submitted with the weekly pile driving report.

The final results of SFV measurements from each foundation installation must be submitted as soon as possible, but no later than 90 days following completion of each event's SFV measurements. The final reports must include all details prescribed above for the interim report as well as, at minimum, the following: the peak

sound pressure level (SPL_{pk}), the root-mean-square sound pressure level that contains 90 percent of the acoustic energy (SPL_{rms}), the single strike sound exposure level (SEL_{ss}), the integration time for SPL_{rms}, the spectrum, and the 24-hour cumulative SEL extrapolated from measurements at all hydrophones. The final report must also include at least the maximum, mean, minimum, median (L_{50}) and L_5 (95 percent exceedance) statistics for each metric, the SEL and SPL power spectral density and/or one-third octave band levels (usually calculated as decidecade band levels) at the receiver locations should be reported, the sound levels reported must be in median, arithmetic mean, and L_5 (95 percent exceedance) (*i.e.,* average in linear space), and in dB, range of transmission loss coefficients, the local environmental conditions, such as wind speed, transmission loss data collected on-site (or the sound velocity profile), baseline pre- and post-activity ambient sound levels (broadband and/or within frequencies of concern), a description of depth and sediment type, as documented in the Construction and Operation Plan (COP), at the recording and foundation installation locations, the extents of the measured Level A harassment and Level B harassment zone(s), hammer energies required for pile installation and the number of strikes per pile, the hydrophone equipment and methods (*i.e.,* recording device, bandwidth/sampling rate; distance from the pile where recordings were made; the depth of recording device(s)), a description of the SFV measurement hardware and software, including software version used, calibration data, bandwidth capability and sensitivity of hydrophone(s), any filters used in hardware or software, any limitations with the equipment, and other relevant information; the spatial configuration of the noise attenuation device(s) relative to the pile, a description of the noise abatement system and operational parameters (*e.g.,* bubble flow rate, distance deployed from the pile, *etc.*), and any action taken to adjust the noise abatement system. A discussion which includes any observations which are suspected to have a significant impact on the results including but not limited to: observed noise mitigation system issues, obstructions along the measurement transect, and technical issues with hydrophones or recording devices.

If at any time during the project Vineyard Wind becomes aware of any issue(s) that may (to any reasonable subject-matter expert, including the persons performing the measurements and analysis) call into question the validity of any measured Level A harassment or Level B harassment isopleths to a significant degree, which were previously transmitted or communicated to NMFS OPR, Vineyard Wind must inform NMFS OPR within 1 business day of becoming aware of this issue or before the next pile is driven, whichever comes first.

Weekly Report—During foundation installation activities, Vineyard Wind would be required to compile and submit weekly marine mammal monitoring reports for foundation installation pile driving to NMFS OPR that document the daily start and stop of all pile driving activities, the start and stop of associated observation periods by PSOs, details on the deployment of PSOs, a record of all detections of marine mammals (acoustic and visual), any mitigation actions (or if mitigation actions could not be taken, provide reasons why), and details on the noise abatement system(s) (*e.g.,* system type, distance deployed from the pile, bubble rate, *etc.*). Weekly reports will be due on Wednesday for the previous week (Sunday to Saturday). The weekly reports are also required to identify which turbines become operational and when (a map must be provided).

Monthly Report—Vineyard Wind would be required to compile and submit monthly reports to NMFS OPR that include a summary of all information in the weekly reports, including project activities carried out in the previous month, vessel transits (number, type of vessel, and route), number of piles installed, all detections of marine mammals, and any mitigative actions taken. Monthly reports would be due on the 15th of the month for the previous month. The monthly report would also identify which turbines become operational and when (a map must be provided).

Final Annual Reporting—Vineyard Wind would be required to submit its draft annual report to NMFS OPR on all visual and acoustic monitoring conducted under the IHA within 90 calendar days of the completion of activities occurring under the IHA. A final annual report must be prepared and submitted within 60 calendar days following receipt of any NMFS comments on the draft report. Information contained within this report is described at the beginning of this section.

Situational Reporting—Specific situations encountered during the Project would require immediate reporting. For instance, if a NARW is sighted with no visible injuries or entanglement at any time by project PSOs or project personnel, Vineyard Wind must immediately report the sighting to NMFS as soon as possible or within 24 hours after the initial sighting. All NARW acoustic detections within a 24-hour period should be collated into one spreadsheet and reported to NMFS as soon as possible but must be reported within 24 hours. Vineyard Wind should report sightings and acoustic detections by downloading and completing the Real-Time NARW Reporting Template spreadsheet found here: *https://www.fisheries.noaa.gov/resource/document/template-datasheet-real-time-north-atlantic-right-whale-acoustic-and-visual.* Vineyard Wind would save the completed spreadsheet as a ''.csv'' file and email it to NMFS Northeast Fisheries Science Center Protected Resources Division (NEFSC–PRD (*ne.rw.survey@noaa.gov*), NMFS Greater Atlantic Regional Fisheries Office (GARFO)-PRD (*nmfs.gar.incidental-take@noaa.gov*), and NMFS OPR (*pr.itp.monitoringreports@noaa.gov*). If the sighting is in the southeast (North Carolina through Florida), sightings should be reported via the template and to the Southeast Hotline 877–WHALE–HELP (877–942–5343) with the observation information provided below (PAM detections are not reported to the Hotline). If Vineyard Wind is unable to report a sighting through the spreadsheet within 24 hours, Vineyard Wind should call the relevant regional hotline (Greater Atlantic Region [Maine through Virginia] Hotline 866–755–6622; Southeast Hotline 877–WHALE–HELP) with the observation information provided below. Observation information would include: the time (note time format), date (MM/DD/YYYY), location (latitude/longitude in decimal degrees; coordinate system used) of the observation, number of whales, animal description/certainty of observation (follow up with photos/video if taken), reporter's contact information, and lease area number/project name, PSO/personnel name who made the observation, and PSO provider company (if applicable). If Vineyard Wind is unable to report via the template or the regional hotline, Vineyard Wind would enter the sighting via the WhaleAlert app (*https://www.whalealert.org/*). If this is not possible, the sighting should be reported to the U.S. Coast Guard via channel 16. The report to the Coast Guard must include the same information as would be reported to the hotline (see above). PAM detections would not be reported to WhaleAlert or the U.S. Coast Guard. If a non-NARW large whale is observed,

Vineyard Wind would be required to report the sighting via WhaleAlert app (*https://www.whalealert.org/*) as soon as possible but within 24 hours.

In the event that personnel involved in the Project discover a stranded, entangled, injured, or dead marine mammal, Vineyard Wind must immediately report the observation to NMFS. If in the Greater Atlantic Region (Maine through Virginia), call the NMFS Greater Atlantic Stranding Hotline (866–755–6622), and if in the Southeast Region (North Carolina through Florida) call the NMFS Southeast Stranding Hotline (877–WHALE–HELP, 877–942–5343). Separately, Vineyard Wind must report the incident within 24 hours to NMFS OPR (*PR.ITP.MonitoringReports@noaa.gov*) and, if in the Greater Atlantic Region to the NMFS GARFO (*nmfs.gar.incidental-take@noaa.gov*) or if in the Southeast Region, to the NMFS Southeast Regional Office (SERO; *secmammalreports@noaa.gov*). Note, the stranding hotline may request the report be sent to the local stranding network response team. The report must include contact information (*e.g.,* name, phone number, *etc.*), time, date, and location (*i.e.,* specify coordinate system) of the first discovery (and updated location information, if known and applicable), species identification (if known) or description of the animal(s) involved, condition of the animal(s) (including carcass condition if the animal is dead), observed behaviors of the animal(s) (if alive), photographs or video footage of the animal(s) (if available), and general circumstances under which the animal was discovered.

If the injury, entanglement, or death was caused by a project activity, Vineyard Wind would be required to immediately cease all activities until NMFS OPR is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. NMFS OPR may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance consistent with the adaptive management provisions. Vineyard Wind could not resume their activities until notified by NMFS OPR.

In the event of a suspected or confirmed vessel strike of a marine mammal by any vessel associated with the Project or other means by which Project activities caused a non-auditory injury or death of a marine mammal, Vineyard Wind must immediately report the incident to NMFS. If in the Greater Atlantic Region (Maine through Virginia), call the NMFS Greater Atlantic Stranding Hotline (866–755–6622), and if in the Southeast Region (North Carolina through Florida) call the NMFS Southeast Stranding Hotline (877–WHALE–HELP, 877–942–5343). Separately, Vineyard Wind must immediately report the incident to NMFS OPR (*PR.ITP.MonitoringReports@noaa.gov*) and, if in the Greater Atlantic Region to the NMFS GARFO (*nmfs.gar.incidental-take@noaa.gov*) or if in the Southeast Region, to the NMFS SERO (*secmammalreports@noaa.gov*). The report must include time, date, and location (*i.e.,* specify coordinate system)) of the incident, species identification (if known) or description of the animal(s) involved (*i.e.,* identifiable features including animal color, presence of dorsal fin, body shape and size, *etc.*), vessel strike reporter information (name, affiliation, email for person completing the report), vessel strike witness (if different than reporter) information (*e.g.,* name, affiliation, phone number, platform for person witnessing the event, *etc.*), vessel name and/or MMSI number; vessel size and motor configuration (inboard, outboard, jet propulsion), vessel's speed leading up to and during the incident, vessel's course/heading and what operations were being conducted (if applicable), part of vessel that struck marine mammal (if known), vessel damage notes, status of all sound sources in use at the time of the strike, if the marine mammal was seen before the strike event, description of behavior of the marine mammal before the strike event (if seen) and behavior immediately following the strike, description of avoidance measures/requirements that were in place at the time of the strike and what additional measures were taken, if any, to avoid strike, environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, visibility, *etc.*) immediately preceding the strike, estimated (or actual, if known) size and length of marine mammal that was struck, if available, description of the presence and behavior of any other marine mammals immediately preceding the strike, other animal-specific details if known (*e.g.,* length, sex, age class), behavior or estimated fate of the marine mammal post-strike (*e.g.,* dead, injured but alive, injured and moving, external visible wounds (linear wounds, propeller wounds, non-cutting blunt-force trauma wounds), blood or tissue observed in the water, status unknown, disappeared), to the extent practicable, any photographs or video footage of the marine mammal(s), and, any additional notes the witness may have from the interaction. For any numerical values provided (*i.e.,* location, animal length, vessel length, *etc.*), please provide if values are actual or estimated.

Vineyard Wind would be required to immediately cease activities until the NMFS OPR is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. NMFS OPR may impose additional measures to minimize the likelihood of further prohibited take and ensure MMPA compliance. Vineyard Wind may not resume their activities until notified by NMFS OPR.

Sound Field Verification—Vineyard Wind would be required to submit interim SFV reports after each foundation installation within 48 hours. A final SFV report for all monopile foundation installation monitoring would be required within 90 days following completion of acoustic monitoring.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

In the Estimated Take section, we estimated the maximum number of takes by Level A harassment and Level B harassment that could occur from Vineyard Wind's specified activities based on the methods described. The impact that any given take would have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts to individuals, *etc.*). In this notice of proposed IHA, we evaluate the likely impacts of the harassment takes that are proposed to be authorized in the context of the specific circumstances surrounding these predicted takes. We also collectively evaluate this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific discussions that support our negligible impact conclusions for each stock. As described above, no serious injury or mortality is expected or proposed to be authorized for any species or stock.

We base our analysis and preliminary negligible impact determination on the number of takes that are proposed to be authorized, and extensive qualitative consideration of other contextual factors that influence the degree of impact of the takes on the affected individuals and the number and context of the individuals affected.

To avoid repetition, we provide some general analysis in this Negligible Impact Analysis and Determination section that applies to all the species listed in table 3 given that some of the anticipated effects of Vineyard Wind's construction activities on marine mammals are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks—as is the case of the NARW—they are included as separate subsections below.

Last, we provide a negligible impact determination for each species or stock, providing species or stock-specific information or analysis where appropriate, for example for NARWs given the population status. Organizing our analysis by grouping species or stocks that share common traits or that would respond similarly to effects of Vineyard Wind's activities, and then providing species- or stock-specific information allows us to avoid duplication while ensuring that we have analyzed the effects of the specified activities on each affected species or stock.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized in this IHA. Any Level A harassment proposed to be authorized would be in the form of auditory injury (*i.e.,* PTS). For all species, the amount of take proposed to be authorized represents the maximum amount of Level A harassment and Level B harassment that is reasonably expected to occur.

Behavioral Disturbance

In general, NMFS anticipates that impacts on an individual that has been harassed are likely to be more intense when exposed to higher received levels and for a longer duration (though this is in no way a strictly linear relationship for behavioral effects across species, individuals, or circumstances) and less severe impacts result when exposed to lower received levels and for a brief duration. However, there is also growing evidence of the importance of contextual factors such as distance from a source in predicting marine mammal behavioral response to sound—*i.e.,* sounds of a similar level emanating from a more distant source have been shown to be less likely to evoke a response of equal magnitude (DeRuiter and Doukara, 2012; Falcone *et al.,* 2017). As described in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, the intensity and duration of any impact resulting from exposure to Vineyard Wind's activities is dependent upon a number of contextual factors including, but not limited to, sound source frequencies, whether the sound source is moving towards the animal, hearing ranges of marine mammals, behavioral state at time of exposure, status of individual exposed (*e.g.,* reproductive status, age class, health) and an individual's experience with similar sound sources. Southall *et al.* (2021), Ellison *et al.* (2012) and Moore and Barlow (2013), among others, emphasize the importance of context (*e.g.,* behavioral state of the animals, distance from the sound source) in evaluating behavioral responses of marine mammals to acoustic sources. Level B Harassment of marine mammals may consist of behavioral modifications (*e.g.,* avoidance, temporary cessation of foraging or communicating, changes in respiration or group dynamics, masking) and may include auditory impacts in the form of temporary hearing loss. In addition, some of the lower-level physiological stress responses (*e.g.,* change in respiration, change in heart rate) discussed previously would likely co-occur with the behavioral modifications, although these physiological responses are more difficult to detect, and fewer data exist relating these responses to specific received levels of sound. Take by Level B harassment, then, may have a stress-related physiological component as well; however, we would not expect Vineyard Wind's pile driving activities to produce conditions of long-term and continuous exposure to noise leading to long-term physiological stress responses in marine mammals that could affect reproduction or survival.

In the range of behavioral effects that might be expected to be part of a response that qualifies as an instance of Level B harassment (which by nature of the way it is modeled/counted, occurs within 1 day), the less severe end might include exposure to comparatively lower levels of a sound, at a greater distance from the animal, for a few or several minutes. A less severe exposure of this nature could result in a behavioral response such as avoiding an area that an animal would otherwise have chosen to move through or feed in for some amount of time or breaking off one or a few feeding bouts. More severe effects could occur if an animal gets close enough to the source to receive a comparatively higher level, is exposed continuously to one source for a longer time or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

Many species perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure, when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat, are more likely to be significant if they last more than 1 day or recur on subsequent days (Southall *et al.,* 2007) due to diel and lunar patterns in diving and foraging behaviors observed in many cetaceans (Baird *et al.,* 2008; Barlow *et al.,* 2020; Henderson *et al.,* 2016; Schorr *et al.,* 2014). It is important to note the water depth in the LIA is shallow (ranging up to 37 to 49.5 m), so deep diving species such as sperm whales are not expected to be engaging in deep foraging dives when exposed to noise above NMFS harassment thresholds during the specified activities. Therefore, we do not anticipate impacts to deep foraging behavior to be impacted by the specified activities.

It is also important to identify that the estimated number of takes does not necessarily equate to the number of individual animals Vineyard Wind expects to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level B harassment thresholds) that may occur. Some individuals of a species may experience recurring instances of take over multiple days throughout the year while some members of a species or stock may experience one exposure as they move through an area, which means that the number of individuals taken is smaller than the total estimated takes. In short, for species that are more likely to be migrating through the area and/or for which only a comparatively smaller number of takes are predicted (*e.g.,* some of the mysticetes), it is more likely that each take represents a different individual whereas for non-migrating species with larger amounts of predicted take, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some would be taken across multiple days.

Impact pile driving for foundation installation is anticipated to have the greatest impacts. For these reasons, impacts are proposed to be minimized through implementation of mitigation measures, including use of a sound attenuation system, soft-starts, the implementation of clearance zones that would facilitate a delay to pile driving commencement, and implementation of shutdown zones. All these measures are designed to avoid or minimize harassment. For example, given sufficient notice through the use of soft-start, marine mammals are expected to move away from a sound source that is disturbing prior to becoming exposed to very loud noise levels. The requirement to couple visual monitoring and PAM before and during all foundation installation will increase the overall capability to detect marine mammals compared to one method alone.

Occasional, milder behavioral reactions are unlikely to cause long-term consequences for individual animals or populations, and even if some smaller subset of the takes is in the form of a longer (several hours or a day) and more severe response, if they are not expected to be repeated over numerous or sequential days, impacts to individual fitness are not anticipated. Also, the effect of disturbance is strongly influenced by whether it overlaps with biologically important habitats when individuals are present—avoiding biologically important habitats will provide opportunities to compensate for reduced or lost foraging (Keen *et al.,* 2021). Nearly all studies and experts agree that infrequent exposures of a single day or less are unlikely to impact an individual's overall energy budget (Farmer *et al.,* 2018; Harris *et al.,* 2017; King *et al.,* 2015; National Academy of Science, 2017; New *et al.,* 2014; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015).

Temporary Threshold Shift

TTS is one form of Level B harassment that marine mammals may incur through exposure to US Wind's activities and, as described earlier, the proposed takes by Level B harassment may represent takes in the form of direct behavioral disturbance, TTS, or both. As discussed in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section, in general, TTS can last from a few minutes to days, be of varying degree, and occur across different frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. Impact pile driving is a broadband noise sources but generates sounds in the lower frequency ranges (with most of the energy below 1–2 kHz, but with a small amount energy ranging up to 20 kHz); therefore, in general and all else being equal, we would anticipate the potential for TTS is higher in low-frequency cetaceans (*i.e.,* mysticetes) than other marine mammal hearing groups and would be more likely to occur in frequency bands in which they communicate. However, we would not expect the TTS to span the entire communication or hearing range of any species given that the frequencies produced by these activities do not span entire hearing ranges for any particular species. Additionally, though the frequency range of TTS that marine mammals might sustain would overlap with some of the frequency ranges of their vocalizations, the frequency range of TTS from Vineyard Wind's pile driving activities would not typically span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues for any given species. In addition, the proposed mitigation measures further reduce the potential for TTS in mysticetes.

Generally, both the degree of TTS and the duration of TTS would be greater if the marine mammal is exposed to a higher level of energy (which would occur when the peak dB level is higher or the duration is longer). The threshold for the onset of TTS was discussed previously (see Estimated Take). An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be unlikely considering the proposed mitigation and the nominal speed of the receiving animal relative to the stationary sources such as impact pile driving. The recovery time of TTS is also of importance when considering the potential impacts from TTS. In TTS laboratory studies (as discussed in Potential Effects of Specified Activities on Marine Mammals and Their Habitat), some using exposures of almost an hour in duration or up to 217 SEL, almost all individuals recovered within 1 day (or less, often in minutes), and we note that while the pile driving activities last for hours a day, it is unlikely that most marine mammals would stay in the close vicinity of the source long enough to incur more severe TTS. Overall, given the few instances in which any individual might incur TTS, the low degree of TTS and the short anticipated duration, and the unlikely scenario that any TTS would overlap the entirety of an individual's critical hearing range, it is unlikely that TTS (of the nature expected to result from the project's activities) would result in behavioral changes or other impacts that would impact any individual's (of any hearing sensitivity) reproduction or survival.

Permanent Threshold Shift

NMFS proposes to authorize a very small amount of take by PTS to some marine mammal individuals. The numbers of proposed takes by Level A harassment are relatively low for all marine mammal stocks and species (table 11). We anticipate that PTS may occur from exposure to impact pile driving, which produces sounds that are both impulsive and primarily concentrated in the lower frequency ranges (below 1 kHz) (David, 2006; Krumpel *et al.,* 2021).

There are no PTS data on cetaceans and only one instance of PTS being induced in older harbor seals (Reichmuth *et al.,* 2019). However, available TTS data (of mid-frequency hearing specialists exposed to mid- or high-frequency sounds (Southall *et al.,* 2007, 2019; NMFS, 2018)) suggest that most threshold shifts occur in the frequency range of the source up to one octave higher than the source. We would anticipate a similar result for PTS. Further, no more than a small degree of PTS is expected to be associated with any of the incurred Level A harassment, given it is unlikely that animals would stay in the close vicinity of a source for a duration long enough to produce more than a small degree of PTS.

PTS would consist of minor degradation of hearing capabilities

occurring predominantly at frequencies one-half to one octave above the frequency of the energy produced by pile driving (*i.e.,* the low-frequency region below 2 kHz) (Cody and Johnstone, 1981; McFadden, 1986; Finneran, 2015), not severe hearing impairment. If hearing impairment occurs from impact pile driving, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. In addition, during impact pile driving, given sufficient notice through use of soft-start prior to implementation of full hammer energy during impact pile driving, marine mammals are expected to move away from a sound source that is disturbing prior to it resulting in severe PTS.

Auditory Masking or Communication Impairment

The potential impacts of masking on an individual are similar to those discussed for TTS (*e.g.,* decreased ability to communicate, forage effectively, or detect predators), but an important difference is that masking only occurs during the period of the signal, versus TTS, which continues beyond the duration of the signal. Also, though masking can result from the sum of exposure to multiple signals, none of these signals might individually cause TTS. Fundamentally, masking is referred to as a chronic effect because one of the key potential harmful components of masking is the fact that an animal would have reduced ability to hear or interpret critical cues. This becomes much more likely to cause a problem the longer it is occurring. Inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further, this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency).

As our analysis has indicated, we expect that impact pile driving may occur for several, albeit intermittent, hours per day, for multiple days. Masking is fundamentally more of a concern at lower frequencies (which are pile driving dominant frequencies), because low-frequency signals propagate significantly further than higher frequencies and because they are more likely to overlap both the narrower low-frequency calls of mysticetes, as well as many non-communication cues related to fish and invertebrate prey, and geologic sounds that inform navigation. As mentioned above (see Description of Marine Mammals in the Area of Specified Activities), the LIA does not overlap critical habitat or BIAs for any species, and temporary avoidance of the pile driving area by marine mammals would likely displace animals to areas of sufficient habitat. In summary, the nature of Vineyard Wind's activities, paired with habitat use patterns by marine mammals, does not support the likelihood of take due to masking effects or that masking would have the potential to affect reproductive success or survival, and are we not proposing to authorize such take.

Impact on Habitat and Prey

Construction activities may result in fish and invertebrate mortality or injury very close to the source, and Vineyard Wind's activities may cause some fish to leave the area of disturbance. It is anticipated that any mortality or injury would be limited to a very small subset of available prey and the implementation of mitigation measures such as the use of a noise attenuation system during impact pile driving would further limit the degree of impact. Behavioral changes in prey in response to construction activities could temporarily impact marine mammals' foraging opportunities in a limited portion of the foraging range but, because of the relatively small area of the habitat that may be affected at any given time (*e.g.,* around a pile being driven) and the temporary nature of the disturbance on prey species, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. There is no indication that displacement of prey would impact individual fitness and health, particularly since unconsumed prey would likely still be available in the environment in most cases following the cessation of acoustic exposure.

Cable presence is not anticipated to impact marine mammal habitat, as these would be buried, and any electromagnetic fields emanating from the cables are not anticipated to result in consequences that would impact marine mammals' prey to the extent they would be unavailable for consumption. Although many species of marine mammal prey can detect electromagnetic fields, previous studies have shown little impacts on habitat use (Hutchinson *et al.,* 2018). Burying the cables and the inclusion of protective shielding on cables will also minimize any impacts of electromagnetic fields on marine mammal prey.

The presence of wind turbines within the Lease Area could have longer-term impacts on marine mammal habitat, as the project would result in the persistence of the structures within marine mammal habitat for more than 30 years. For piscivorous marine mammal species, the presence of structures could result in a beneficial reef effect which may lead to increases in the availability of prey. However, turbine presence and operation is, generally likely to result in certain oceanographic effects in the marine environment, and may adversely alter aggregations and distribution of marine mammal zooplankton prey through changing the strength of tidal currents and associated fronts, changes in stratification, primary production, the degree of mixing, and stratification in the water column (Chen *et al.,* 2021; Johnson *et al.,* 2021; Christiansen *et al.,* 2022; Dorrell *et al.,* 2022). In the recently released BOEM and NOAA Fisheries North Atlantic Right Whale Strategy (BOEM *et al.,* 2024), the agencies identify the conceptual pathway by which changes to ocean circulation could potentially lead to fitness reduction of North Atlantic right whales, who primarily forage on copepods (see figure 2). As described in the *Potential Effects to Marine Mammal Habitat* section, there is uncertainty regarding the intensity (or magnitude) and spatial extent of turbine operation impacts on marine mammals habitat, including planktonic prey. Recently, a National Academy of Sciences, Engineering, and Medicine panel of independent experts concluded that the impacts of offshore wind operations on North Atlantic right whales and their habitat in the Nantucket Shoals region is uncertain due to the limited data available at this time and recognized what data is available is largely based on models from the North Sea that have not been validated by observations (NAS, 2023). The report also identifies that major oceanographic changes have occurred to the Nantucket Shoals region over the past 25 years and it will be difficult to isolate from the much larger variability introduced by natural and other anthropogenic sources (including climate change).

As discussed in the Description of the Specified Activity section, this IHA addresses the take incidental to the installation of 15 foundations, which will gradually become operational following construction completion. While there are likely to be oceanographic impacts from the presence of operating turbines, meaningful oceanographic impacts relative to stratification and mixing that would significantly affect marine

mammal foraging and prey over large areas in key foraging habitats, resulting in the reproduction or survival of any individual marine mammals, are not anticipated from the Vineyard Wind activities covered under this proposed IHA, yet are likely to be comparatively minor, if impacts do occur.

Mitigation To Reduce Impacts on All Species

The proposed IHA includes a variety of mitigation measures designed to minimize impacts on all marine mammals, with a focus on NARWs (the latter is described in more detail below). For impact pile driving of foundation piles, 10 overarching mitigation measures are proposed, which are intended to reduce both the number and intensity of marine mammal takes: (1) seasonal/time of day work restrictions; (2) use of multiple PSOs to visually observe for marine mammals (with any detection within specifically designated zones triggering a delay or shutdown); (3) use of PAM to acoustically detect marine mammals, with a focus on detecting baleen whales (with any detection within designated zones triggering delay or shutdown); (4) implementation of clearance zones; (5) implementation of shutdown zones; (6) use of soft-start; (7) use of noise attenuation technology; (8) maintaining situational awareness of marine mammal presence through the requirement that any marine mammal sighting(s) by Vineyard Wind's personnel must be reported to PSOs; (9) sound field verification monitoring; and (10) Vessel Strike Avoidance measures to reduce the risk of a collision with a marine mammal and vessel.

The Proposed Mitigation section discusses the manner in which the required mitigation measures reduce the magnitude and/or severity of the take of marine mammals, including the following. For activities with large harassment isopleths, Vineyard Wind would be required to reduce the noise levels generated to the lowest levels practicable. Use of a soft-start during impact pile driving will allow animals to move away from (*i.e.,* avoid) the sound source prior to applying higher hammer energy levels needed to install the pile (Vineyard Wind would not use a hammer energy greater than necessary to install piles). Clearance zone and shutdown zone implementation, which are required when marine mammals are within given distances associated with certain impact thresholds for all activities, would reduce the magnitude and severity of marine mammal take. Additionally, the use of multiple PSOs, PAM, and maintaining awareness of marine mammal sightings reported in the region would aid in detecting marine mammals that would trigger the implementation of the mitigation measures.

Mysticetes

Five mysticete species (comprising five stocks) of cetaceans (NARW, humpback whale, fin whale, sei whale, and minke whale) may be taken by harassment. These species, to varying extents, utilize the specific geographic region, including the LIA, for the purposes of migration, foraging, and socializing. Mysticetes are in the low-frequency hearing group.

Behavioral data on mysticete reactions to pile driving noise are scant. Kraus *et al.* (2019) predicted that the three main impacts of offshore wind farms on marine mammals would consist of displacement, behavioral disruptions, and stress. Broadly, we can look to studies that have focused on other noise sources such as seismic surveys and military training exercises, which suggest that exposure to loud signals can result in avoidance of the sound source (or displacement if the activity continues for a longer duration in a place where individuals would otherwise have been staying, which is less likely for mysticetes in this area), disruption of foraging activities (if they are occurring in the area), local masking around the source, associated stress responses, and impacts to prey, as well as TTS or PTS in some cases.

Mysticetes encountered in the LIA are expected to be migrating through and/or engaged in foraging behavior. The extent to which an animal engages in these behaviors in the area is species-specific and varies seasonally. Many mysticetes are expected to predominantly be migrating through the LIA towards or from primary feeding habitats (*e.g.,* Cape Cod Bay, Great South Channel, and Gulf of St. Lawrence). While we have acknowledged above that mortality, hearing impairment, or displacement of mysticete prey species may result locally from impact pile driving, given the very short duration of and broad availability of prey species in the area and the availability of alternative suitable foraging habitat for the mysticete species most likely to be affected, any impacts on mysticete foraging are expected to be minor. Whales temporarily displaced from the LIA are expected to have sufficient remaining feeding habitat available to them, and would not be prevented from feeding in other areas within the biologically important feeding habitats, including to the east near Nantucket Shoals. In addition, any displacement of whales or interruption of foraging bouts would be expected to be relatively temporary in nature.

The potential for repeated exposures of individuals is dependent upon their residency time, with migratory animals unlikely to be exposed on repeated occasions and animals remaining in the area more likely to be exposed more than once. For mysticetes, where relatively low numbers of species-specific take by Level B harassment are predicted (compared to the abundance of each mysticete species or stock; see table 11) and movement patterns suggest that individuals would not necessarily linger in a particular area for multiple days, each predicted take likely represents an exposure of a different individual; with perhaps a subset of takes for a few species potentially representing a few repeated of a limited number of individuals across multiple days. In other words, the behavioral disturbance to any individual mysticete would, therefore, be expected to most likely occur within a single day, or potentially across a few days, and therefore would not be expected to impact the animal's fitness for reproduction or survival.

In general, the duration of exposures would not be continuous throughout any given day and pile driving would not occur on all consecutive days due to weather delays or any number of logistical constraints Vineyard Wind has identified. Species-specific analysis regarding potential for repeated exposures and impacts is provided below.

Humpback whales, minke whales, fin whales and sei whales are the mysticete species for which PTS is anticipated and proposed to be authorized. As described previously, PTS for mysticetes from some project activities may overlap frequencies used for communication, navigation, or detecting prey. However, given the nature and duration of the activity, the mitigation measures, and likely avoidance behavior, any PTS is expected to be of a small degree, would be limited to frequencies where pile driving noise is concentrated (*i.e.,* only a small subset of their expected hearing range) and would not be expected to impact individuals' fitness for reproductive success or survival.

NARWs

NARWs are listed as endangered under the ESA and as both depleted and strategic under the MMPA. As described in the Potential Effects to Marine Mammals and Their Habitat section, NARWs are threatened by a low population abundance, higher than

average mortality rates, and lower than average reproductive rates. Recent studies have reported individuals showing high stress levels (*e.g.,* Corkeron *et al.,* 2017) and poor health, which has further implications on reproductive success and calf survival (Christiansen *et al.,* 2020; Stewart *et al.,* 2021, 2022). As described below, a UME has been designated for NARWs. Given this, the status of the NARW population is of heightened concern and, therefore, merits additional analysis and consideration.

This proposed IHA would authorize seven takes of NARW by Level B harassment only, which equates to approximately 2.1 percent of the stock's abundance, if each take were considered to be of a different individual. No Level A harassment, serious injury, or mortality is anticipated or proposed to be authorized for this species.

As described in the Description of Marine Mammals in the Area of Specified Activities section, NARWs are presently experiencing an ongoing UME (beginning in June 2017). Preliminary findings support human interactions, specifically vessel strikes and entanglements, as the cause of death for the majority of NARWs. Given the current status of the NARW, the loss of even one individual could significantly impact the population. Level B harassment of NARWs resulting from the Project's activities is expected to primarily be in the form of temporary avoidance of the immediate area of construction. Required mitigation measures will ensure the least practicable adverse impact and the proposed number of takes of NARWs would not exacerbate or compound the effects of the ongoing UME.

In general, NARWs in the LIA are expected to be engaging in migratory, feeding, and/or social behavior. Migrating NARWs would typically be moving through the LIA, rather than lingering for extended periods of time (thereby limiting the potential for repeat exposures); however, foraging whales may remain in the LIA, with an average residence time of 13 days between December and May (Quintana-Rizzo *et al.,* 2021). SNE, including the LIA, is part of a known migratory corridor for NARWs and may be a stopover site for migrating NARWs moving to or from southeastern calving grounds and northern foraging grounds. NARWs are primarily concentrated in the northeastern and southeastern sections of the Massachusetts Wind Energy Area (MA WEA) (*i.e.,* east of the LIA) during the summer (June-August) and winter (December-February) while distribution likely shifts to the west, closer to the LIA, into the Rhode Island/Massachusetts Wind Energy Area (RI/MA WEA) in the spring (March-May) (Quintana-Rizzo *et al.,* 2021). However, NARWs range outside of the LIA for their main feeding, breeding, and calving activities. It is important to note that there would be a restriction on impact pile driving activities from January through May, with pile driving only allowed in December with approval from NMFS and BOEM.

Foundation installation is of concern, given loud sound levels. However, as described above, foundation installation would only occur during times when, based on the best available scientific data, NARWs are less frequently encountered and less likely to be engaged in critical foraging behavior (although NMFS recognizes NARWs may forage year-round in SNE). The potential types, severity, and magnitude of impacts are also anticipated to mirror that described in the general *Mysticetes* section above, including avoidance (the most likely outcome), changes in foraging or vocalization behavior, masking, a small amount of TTS, and temporary physiological impacts (*e.g.,* change in respiration, change in heart rate). Importantly, the effects of the activities are expected to be sufficiently low-level and localized to specific areas as to not meaningfully impact important behaviors such as migration and foraging for NARWs. As noted above, for NARWs, this IHA would authorize up to seven takes, by Level B harassment. These takes are expected to be in the form of temporary behavioral disturbance, such as slight displacement (but not abandonment) of migratory habitat or temporary cessation of feeding. Further, given many of these exposures are generally expected to occur to different individual right whales migrating through (*i.e.,* many individuals would not be impacted on more than 1 day in a year), with some subset potentially being exposed on no more than a few days within the year, they are unlikely to result in energetic consequences that could affect reproduction or survival of any individuals.

Overall, NMFS expects that any behavioral harassment of NARWs incidental to the specified activities would not result in changes to their migration patterns or foraging success, as only temporary avoidance of an area during construction is expected to occur. As described previously, NARWs migrate, forage, or socialize in the LIA but are not expected to remain in this habitat for extensive durations relative to core foraging habitats to the east, south of Nantucket and Martha's Vineyard, Cape Cod Bay, or the Great South Channel (Quintana-Rizzo *et al.,* 2021). Any temporarily displaced animals would be able to return to or continue to travel through the LIA and subsequently utilize this habitat once activities have ceased.

Although acoustic masking may occur in the vicinity of the foundation installation activities, based on the acoustic characteristics of noise associated with pile driving (*e.g.,* frequency spectra, short duration of exposure, NMFS expects masking effects to be minimal during impact pile driving). In addition, masking would likely only occur during the period of time that a NARW is in the relatively close vicinity of pile driving, which is expected to be intermittent within a day and confined to the months in which NARWs are at lower densities and primarily moving through the area. TTS,could also occur in some of the exposed animals, making it more difficult for those individuals to hear or interpret acoustic cues within the frequency range (and slightly above) of sound produced during impact pile driving; however, any TTS would likely be of low amount, limited duration, and limited to frequencies where most construction noise is centered (below 2 kHz). NMFS expects that right whale hearing sensitivity would return to pre-exposure levels shortly after migrating through the area or moving away from the sound source.

As described in the Potential Effects to Marine Mammals and Their Habitat section of this notice, the distance of the receiver from the source influences the severity of response, with greater distances typically eliciting less severe responses. NMFS recognizes NARWs migrating could be pregnant females (in the fall) and cows with older calves (in spring) and that these animals may slightly alter their migration course in response to any foundation pile driving; however, we anticipate that course diversion would be of small magnitude. Hence, while some avoidance of the pile-driving activities may occur, we anticipate any avoidance behavior of migratory NARWs would be similar to that of gray whales (Tyack *et al.,* 1983), on the order of hundreds of meters up to 1 to 2 km. This diversion from a migratory path otherwise uninterrupted by the project's activities is not expected to result in meaningful energetic costs that would impact annual rates of recruitment of survival. NMFS expects that NARWs would be able to avoid areas during periods of active noise production while not being forced out of this portion of their habitat.

NARW presence in the LIA is year-round. However, abundance during summer months is lower compared to the winter months with spring and fall serving as ''shoulder seasons'' wherein abundance waxes (fall) or wanes (spring). Even in consideration of recent habitat use and distribution shifts, Vineyard Wind would still be installing monopile foundations when the presence of NARWs is expected to be lower.

Given this year-round habitat usage, in recognition that where and when whales may actually occur during project activities is unknown as it depends on the annual migratory behaviors, NMFS is requiring a suite of mitigation measures designed to reduce impacts to NARWs to the maximum extent practicable. These mitigation measures (*e.g.,* seasonal/daily work restrictions, vessel separation distances, and reduced vessel speed) would not only avoid the likelihood of vessel strikes but also would minimize the severity of behavioral disruptions (*e.g.,* through sound reduction using attenuation systems and reduced temporal overlap of project activities and NARWs). This would help further ensure that takes by Level B harassment that are estimated to occur would not affect reproductive success or survivorship of individuals through detrimental impacts to energy intake or cow/calf interactions during migratory transit.

As described in the Description of Marine Mammals in the Area of Specified Activities section, the Vineyard Wind Offshore Wind Project is being constructed within the NARW migratory corridor BIA, which represents areas and months within which a substantial portion of a species or population is known to migrate. The area over which NARWs may be harassed is relatively small compared to the width of the migratory corridor. The width of the migratory corridor in this area is approximately 210.1 km (while the width of the Lease Area, at the longest point at which it crosses the BIA, is approximately 14.5 km). NARWs may be displaced from their normal path and preferred habitat in the immediate activity area (primarily from pile driving activities), however, we do not anticipate displacement to be of high magnitude (*e.g.,* beyond a few kilometers); therefore, any associated bio-energetic expenditure is anticipated to be small. Although NARWs may forage in the LIA, there are no known breeding or calving areas within the LIA. Prey species are mobile (*e.g.,* calanoid copepods can initiate rapid and directed escape responses) and are broadly distributed throughout the LIA. Therefore, any impacts to prey that may occur are also unlikely to impact marine mammals.

The most significant measure to minimize impacts to individual NARWs is the seasonal moratorium on all foundation installation activities from January 1 through May 31 and the limitation on these activities in December (*e.g.,* only work with approval from NMFS) when NARW abundance in the LIA is expected to be highest. NMFS also expects this measure to greatly reduce the potential for mother-calf pairs to be exposed to impact pile driving noise above the Level B harassment threshold during their annual spring migration through SNE from calving grounds to primary foraging grounds (*e.g.,* Cape Cod Bay). NMFS expects that the severity of any take of NARWs would be reduced due to the mitigation measures that would ensure that any exposures above the Level B harassment threshold would result in only short-term effects to individuals exposed.

Foundation installation may only begin in the absence of NARWs (based on visual and passive acoustic monitoring). Once foundation installation activities have commenced, NMFS anticipates NARWs would avoid the area, utilizing nearby waters to carry on pre-exposure behaviors. However, foundation installation activities must be shut down if a NARW is sighted at any distance or acoustically detected at any distance within the PAM monitoring zone, unless a shutdown is not feasible due to risk of injury or loss of life. Shutdown would be required anywhere if NARWs are detected within or beyond the Level B harassment zone, further minimizing the duration and intensity of exposure. These measures are designed to avoid PTS and also reduce the severity of Level B harassment, including the potential for TTS. While some TTS could occur, given the mitigation measures (*e.g.,* delay pile driving upon a sighting or acoustic detection and shutting down upon a sighting or acoustic detection), the potential for TTS to occur is low. NMFS anticipates that if NARWs go undetected and they are exposed to foundation installation noise, it is unlikely a NARW would approach the sound source locations to the degree that they would expose themselves to very high noise levels. This is because typical observed whale behavior demonstrates likely avoidance of harassing levels of sound where possible (Richardson *et al.,* 1985).

The clearance and shutdown measures are most effective when detection efficiency is maximized, as the measures are triggered by a sighting or acoustic detection. To maximize detection efficiency, NMFS would require the combination of PAM and visual observers. NMFS also would require communication protocols with other project vessels and other heightened awareness efforts (*e.g.,* daily monitoring of NARW sighting databases) such that as a NARW approaches the source (and thereby could be exposed to higher noise energy levels), PSO detection efficacy would increase, the whale would be detected, and a delay to commencing foundation installation or shutdown (if feasible) would occur. In addition, the implementation of a soft-start for impact pile driving would provide an opportunity for whales to move away from the source if they are undetected, reducing received levels.

As described above, no serious injury or mortality, or Level A harassment of NARWs is anticipated or proposed to be authorized. Extensive NARW-specific mitigation measures (beyond the robust suite required for all species) are expected to further minimize the amount and severity of Level B harassment.

Given the documented habitat use within the LIA, the seven instances of take by Level B harassment could include seven whales disturbed on one day each within the year, or it could represent a smaller number of whales impacted on 2 or 3 days, should NARWs briefly use the LIA as a ''stopover'' site and stay or swim in and out of the LIA for more than day. At any rate, any impacts to NARWs are expected to be in the form of lower level behavioral disturbance, given the extensive mitigation measures.

Given the magnitude and severity of the impacts discussed above, and in consideration of the required mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take (by Level B harassment) anticipated and proposed to be authorized would have a negligible impact on the NARW.

Fin Whale

The fin whale is listed as endangered under the ESA, and the western North Atlantic stock is considered both depleted and strategic under the MMPA. No UME has been designated for this species or stock. No serious injury or

mortality is anticipated or proposed to be authorized for this species.

This IHA would authorize up to seven takes, by harassment only, over the 1 year period. The maximum allowable take by Level A harassment and Level B harassment, is one and six, respectively (which equates to approximately 0.10 percent of the stock abundance, if each take were considered to be of a different individual). Given the close proximity of a fin whale feeding BIA (2,933 km^2) from March through October, and that SNE is generally considered a feeding area, it is likely that the seven takes could represent a few whales taken 2–3 times annually.

Level B harassment is expected to be in the form of behavioral disturbance, primarily avoidance of the LIA where foundation installation is occurring and some low-level TTS and masking that may limit the detection of acoustic cues for relatively brief periods of time. We anticipate any potential PTS would be minor (limited to a few dB), and any PTS or TTS would be concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of fin whales. If TTS is incurred, hearing sensitivity would likely return to pre-exposure levels relatively shortly after exposure ends. Any masking or physiological responses would also be of low magnitude and severity for reasons described above.

Fin whales are present in the waters off of New England year-round and are one of the most frequently observed large whales and cetaceans in continental shelf waters, principally from Cape Hatteras, North Carolina in the Mid-Atlantic northward to Nova Scotia, Canada (Sergeant, 1977; Sutcliffe and Brodie, 1977; CETAP, 1982; Hain *et al.,* 1992; Geo-Marine, 2010; BOEM 2012; Edwards *et al.,* 2015; Hayes *et al.,* 2023). In SNE, fin whales densities are highest in the spring and summer months (Kraus *et al.,* 2016; Roberts *et al.,* 2023) though detections do occur in spring and fall (Watkins *et al.,* 1987; Clark and Gagnon, 2002; Geo-Marine, 2010; Morano *et al.,* 2012; Van Parijs *et al.,* 2023). However, fin whales feed more extensively in waters in the Great South Channel north to the Gulf Maine into the Gulf of St. Lawrence, areas north and east of the LIA (Hayes *et al.,* 2023).

As described previously, the LIA is in close proximity (approximately 8.0 km; 5.0 mi) to a small fin whale feeding BIA (2,933 km^2) east of Montauk Point, New York (figure 2.3 in LaBrecque *et al.,* 2015) that is active from March to October. Foundation installations have seasonal work restrictions (*i.e.,* spatial and temporal) such that the temporal overlap between the specified activities and the active BIA timeframe would exclude the months of March, April, and May. A separate larger year-round feeding BIA (18,015 km^2) located to the east in the southern Gulf of Maine does not overlap with the LIA and is located substantially further away (approximately 76.4 km (47.5 mi)), and would thus not be impacted by project activities. We anticipate that if foraging is occurring in the LIA and foraging whales are exposed to noise levels of sufficient strength, they would avoid the LIA and move into the remaining area of the feeding BIA that would be unaffected to continue foraging without substantial energy expenditure or, depending on the time of year, travel to the larger year-round feeding BIA.

Given the documented habitat use within the area, some of the individuals taken would likely be exposed on multiple days. However, low level impacts are generally expected from any fin whale exposure. Given the magnitude and severity of the impacts discussed above (including no more than seven takes over the course of the IHA, and a maximum allowable take by Level A harassment and Level B harassment of one and six, respectively) and in consideration of the required mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on the western North Atlantic stock of fin whales.

Humpback Whale

The West Indies DPS of humpback whales is not listed as threatened or endangered under the ESA but the Gulf of Maine stock, which includes individuals from the West Indies DPS, is considered strategic under the MMPA. However, as described in the Description of Marine Mammals in the Area of Specified Activities section, humpback whales along the Atlantic Coast have been experiencing an active UME as elevated humpback whale mortalities have occurred along the Atlantic coast from Maine through Florida since January 2016. Of the cases examined, approximately 40 percent had evidence of human interaction (vessel strike or entanglement). Despite the UME, the relevant population of humpback whales (the West Indies breeding population, or DPS of which the Gulf of Maine stock is a part) remains stable at approximately 12,000 individuals and takes of humpback whales proposed for authorization would not exacerbate or compound the effects of the ongoing UME.

This IHA would authorize up to six takes by harassment only, over the 1 year period. The maximum allowable take by Level A harassment and Level B harassment is two and four, respectively (this equates to approximately 0.43 percent of the stock abundance, if each take were considered to be of a different individual). Given that feeding is considered the principal activity of humpback whales in SNE waters, these takes could represent a few whales exposed two or three times during the year.

In the western North Atlantic, humpback whales feed during spring, summer, and fall over a geographic range encompassing the eastern coast of the U.S. Feeding is generally considered to be focused in areas north of the LIA, including in a feeding BIA in the Gulf of Maine/Stellwagen Bank/Great South Channel, but has been documented off the coast of SNE and as far south as Virginia (Swingle *et al.,* 1993). Foraging animals tend to remain in the area for extended durations to capitalize on the food sources.

Assuming humpback whales who are feeding in waters within or surrounding the LIA behave similarly, we expect that the predicted instances of disturbance could consist of some individuals that may be exposed on multiple days if they are utilizing the area as foraging habitat. As with other baleen whales, if migrating, such individuals would likely be exposed to noise levels from the project above the harassment thresholds only once during migration through the LIA.

For all the reasons described in the *Mysticetes* section above, we anticipate any potential PTS and TTS would be concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of baleen whales. If TTS is incurred, hearing sensitivity would likely return to pre-exposure levels relatively shortly after exposure ends. Any masking or physiological responses would also be of low magnitude and severity for reasons described above.

Given the magnitude and severity of the impacts discussed above (including no more than six takes over the course of the 1-year IHA, and a maximum allowable take by Level A harassment and Level B harassment of two and four, respectively), and in consideration of

the proposed mitigation measures and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on the Gulf of Maine stock of humpback whales.

Minke Whale

Minke whales are not listed under the ESA, and the Canadian East Coast stock is neither considered depleted nor strategic under the MMPA. There are no known areas of specific biological importance in or adjacent to the LIA. As described in the Description of Marine Mammals in the Area of Specified Activities section, a UME has been designated for this species but is pending closure. No serious injury or mortality is anticipated or proposed to be authorized for this species.

This IHA would authorize up to 1 take by Level A harassment and 28 takes by Level B harassment over the 1-year period (equating to approximately 0.13 percent of the stock abundance, if each take were considered to be of a different individual). As described in the Description of Marine Mammals in the Area of Specified Activities section, minke whales inhabit coastal waters during much of the year and are common offshore the U.S. eastern seaboard with a strong seasonal component in the continental shelf and in deeper, off-shelf waters (CETAP, 1982; Hayes *et al.,* 2022; Hayes *et al.,* 2023). Spring through fall are times of relatively widespread and common acoustic occurrence on the continental shelf. From September through April, minke whales are frequently detected in deep-ocean waters throughout most of the western North Atlantic (Clark and Gagnon, 2002; Risch *et al.,* 2014; Hayes *et al.,* 2023). Because minke whales are migratory and their known feeding areas are north and east of the LIA, including a feeding BIA in the southwestern Gulf of Maine and George's Bank, they would be more likely to be transiting through (with each take representing a separate individual), though it is possible that some subset of the individual whales exposed could be taken up to a few times during the effective period of the IHA.

As previously detailed in the Description of Marine Mammals in the Area of Specified Activities section, there is a UME for minke whales along the Atlantic coast, from Maine through South Carolina, with the highest number of deaths in Massachusetts, Maine, and New York. Preliminary findings in several of the whales have shown evidence of human interactions or infectious diseases. However, we note that the population abundance is greater than 21,000, and the take by harassment proposed to be authorized through this action is not expected to exacerbate the UME.

We anticipate the impacts of this harassment to follow those described in the general *Mysticetes* section above. Any potential PTS would be minor (limited to a few dB) and any PTS or TTS would be of short duration and concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz) which does not include the full predicted hearing range of minke whales. If TTS is incurred, hearing sensitivity would likely return to pre-exposure levels relatively shortly after exposure ends. Level B harassment would be temporary, with primary impacts being temporary displacement from the LIA but not abandonment of any migratory or foraging behavior.

Given the magnitude and severity of the impacts discussed above (including no more than 29 takes of the course of the 1-year IHA, and a maximum allowable take by Level A harassment and Level B harassment of 1 and 28, respectively), and in consideration of the proposed mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on the Canadian Eastern Coastal stock of minke whales.

Sei Whale

Sei whales are listed as endangered under the ESA, and the Nova Scotia stock is considered both depleted and strategic under the MMPA. There are no known areas of specific biological importance in or adjacent to the LIA, and no UME has been designated for this species or stock. No serious injury or mortality is anticipated or proposed to be authorized for this species.

The IHA would authorize up to three takes by harassment over the 1-year period. The maximum allowable take by Level A harassment and Level B harassment is one and two, respectively (combined, this annual take (n=3) equates to approximately 0.05 percent of the stock abundance, if each take were considered to be of a different individual). As described in the Description of Marine Mammals in the Area of Specified Activities section, most of the sei whale distribution is concentrated in Canadian waters and seasonally in northerly United States waters, although they can occur year-round in SNE. Because sei whales are migratory and their known feeding areas are east and north of the LIA (*e.g.,* there is a feeding BIA in the Gulf of Maine), they would be more likely to be moving through (*i.e.,* not foraging) and considering this and the very low number of total takes, it is unlikely that any individual would be exposed more than once within the effective period of the IHA.

With respect to the severity of those individual takes by Level B harassment, we anticipate impacts to be limited to low-level, temporary behavioral responses with avoidance and potential masking impacts in the vicinity of the WTG installation to be the most likely type of response. Any potential PTS and TTS would likely be concentrated at half or one octave above the frequency band of pile driving noise (most sound is below 2 kHz), which does not include the full predicted hearing range of sei whales. Moreover, any TTS would be of a small degree. Any avoidance of the LIA due to the Project's activities would be expected to be temporary.

Given the magnitude and severity of the impacts discussed above (including no more than three takes of the course of the 1-year IHA, and a maximum allowable take by Level A harassment and Level B harassment, of one and two, respectively), and in consideration of the required mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on the Nova Scotia stock of sei whales.

Odontocetes

In this section, we include information here that applies to all of the odontocete species and stocks addressed below. Odontocetes include dolphins, porpoises, and all other whales possessing teeth and we further divide them into the following subsections: sperm whales, dolphins and small whales, and harbor porpoises. These sub-sections include more specific information, as well as conclusions for each stock represented.

No serious injury or mortality is anticipated or proposed to be authorized. We anticipate that, given

ranges of individuals (*i.e.,* that some individuals remain within a small area for some period of time) and non-migratory nature of some odontocetes in general (especially as compared to mysticetes), a larger subset of these takes are more likely to represent multiple exposures of some number of individuals than is the case for mysticetes, though some takes may also represent one-time exposures of an individual. While we expect animals to avoid the area during foundation installation, their habitat range is extensive compared to the area ensonified during these activities. As such, NMFS expects any avoidance behavior to be limited to the area near the sound source.

As described earlier, Level B harassment may include direct disruptions in behavioral patterns (*e.g.,* avoidance, changes in feeding or vocalizations), as well as those associated with stress responses or TTS. While masking could also occur during foundation installation, it would only occur in the vicinity of and during the duration of the activity, and would not generally occur in a frequency range that overlaps most odontocete communication or any echolocation signals. The proposed mitigation measures (*e.g.,* use of sound attenuation systems, implementation of clearance and shutdown zones) would also minimize received levels such that the expected severity of any behavioral response would be less than exposure to unmitigated noise exposure.

Any masking or TTS effects are anticipated to be of low severity. First, while the frequency range of pile driving falls within a portion of the frequency range of most odontocete vocalizations, odontocete vocalizations span a much wider range than the low frequency construction activities planned for the project. Also, as described above, recent studies suggest odontocetes have a mechanism to self-mitigate the impacts of noise exposure (*i.e.,* reduce hearing sensitivity), which could potentially reduce TTS impacts. Any masking or TTS is anticipated to be limited and would typically only interfere with communication within a portion of an odontocete's range and as discussed earlier, the effects would only be expected to be of a short duration and for TTS, a relatively small degree. Furthermore, odontocete echolocation occurs predominantly at frequencies significantly higher than low frequency construction activities. Therefore, there is little likelihood that threshold shift would interfere with feeding behaviors.

The waters off the coast of Massachusetts are used by several odontocete species. However, none except the sperm whale are listed under the ESA and there are no known habitats of particular importance. In general, odontocete habitat ranges are far-reaching along the Atlantic coast of the U.S. and the waters off of New England, including the LIA, do not contain any particularly unique odontocete habitat features.

Sperm Whale

Sperm whales are listed as endangered under the ESA, and the North Atlantic stock is considered both depleted and strategic under the MMPA. The North Atlantic stock spans the east coast out into oceanic waters well beyond the U.S. EEZ. Although listed as endangered, the primary threat faced by the sperm whale across its range (*i.e.,* commercial whaling) has been eliminated. Current potential threats to the species globally include vessel strikes, entanglement in fishing gear, anthropogenic noise, exposure to contaminants, climate change, and marine debris. There is no currently reported trend for the stock and although the species is listed as endangered under the ESA, there are no current related issues or events associated with the status of the stock that cause particular concern (*e.g.,* no UMEs). There are no known areas of biological importance (*e.g.,* critical habitat or BIAs) in or near the LIA. No mortality or serious injury is anticipated or proposed to be authorized for this species.

The IHA would authorize up to two takes by Level B harassment over the 1-year period, which equates to approximately 0.05 percent of the stock abundance. If sperm whales are present in the LIA during any Project activities, they will likely be only transient visitors, although foraging and social behavior may occur in the shallow waters off SNE (Westell *et al.,* 2024). However, the potential for TTS is low for reasons described in the general Odontocete section. If it does occur, any hearing shift would be small and of a short duration. Because foraging is expected to be rare in the LIA, TTS is not expected to interfere with foraging behavior.

Given the magnitude and severity of the impacts discussed above (including no more than two takes by Level B harassment over the course of the 1-year IHA, and in consideration of the required mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by Level B harassment anticipated and proposed to be authorized will have a negligible impact on the North Atlantic stock of sperm whales.

Dolphins and Small Whales (Including Delphinids)

The five species and stocks included in this group (which are indicated in table 3 in the Delphinidae family) are not listed under the ESA, and nor are they listed as depleted or strategic under the MMPA. There are no known areas of specific biological importance in or around the LIA. As described above for any of these species and no UMEs have been designated for any of these species. No serious injury or mortality is anticipated or proposed to be authorized for these species.

The five delphinid species (constituting five stocks) with takes proposed to be authorized for the Project are Atlantic white-sided dolphin, bottlenose dolphin, long-finned pilot whale, Risso's dolphin, and common dolphin. The IHA would allow for the total authorization of 3 to 462 takes (depending on species) by Level B harassment, over the 1-year period. Overall, this annual take equates to approximately 0.01 (Risso's dolphin) to up to 0.27 (common dolphin) percent of the stock abundance (if each take were considered to be of a different individual, which is not likely the case), depending on the species.

The number of takes, likely movement patterns of the affected species, and the intensity of any Level B harassment, combined with the availability of alternate nearby foraging habitat suggests that the likely impacts would not impact the reproduction or survival of any individuals. While delphinids may be taken on several occasions, none of these species are known to have small home ranges within the LIA or known to be particularly sensitive to anthropogenic noise. Some TTS can occur, but it would be limited to the frequency ranges of the activity and any loss of hearing sensitivity is anticipated to return to pre-exposure conditions shortly after the animals move away from the source or the source ceases.

Across these species, the maximum number of incidental takes, by Level B harassment (no Level A harassment is anticipated or proposed to be authorized), proposed to be authorized ranges between 3 (Risso's dolphin) to 462 (common dolphin). Though the estimated numbers of take are comparatively higher than the numbers for mysticetes, we note that for all

species they are relatively low relative to the population abundance.

As described above for odontocetes broadly, given the number of estimated takes for some species and the behavioral patterns of odontocetes, we anticipate that some of these instances of take in a day represent multiple exposures of a smaller number of individuals, meaning the actual number of individuals taken is lower. Although some amount of repeated exposure to some individuals across a few days within the year is likely, the intensity of any Level B harassment combined with the availability of alternate nearby foraging habitat suggests that the likely impacts would not impact the reproduction or survival of any individuals.

Overall, the populations of all delphinid and small whale species and stocks for which we proposed to authorize take are stable (no declining population trends). None of these stocks are experiencing existing UMEs. No mortality, serious injury, or Level A harassment is anticipated or proposed to be authorized for any of these species. Given the magnitude and severity of the impacts discussed above and in consideration of the required mitigation and other information presented, as well as the status of these stocks, the specified activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on all of the following species and stocks: Atlantic white-sided dolphins, bottlenose dolphins, long-finned pilot whales, Risso's dolphins, and common dolphins.

Harbor Porpoise

Harbor porpoises are not listed as threatened or endangered under the ESA, and the Gulf of Maine/Bay of Fundy stock is neither considered depleted or strategic under the MMPA. The stock is found predominantly in northern United States coastal waters (less than 150 m depth) and up into Canada's Bay of Fundy (between New Brunswick and Nova Scotia). Although the population trend is not known, there are no UMEs or other factors that cause particular concern for this stock. No mortality or non-auditory injury are anticipated or proposed to be authorized for this stock.

The IHA would authorize up to 113 takes, by harassment only. The maximum allowable take by Level A harassment and Level B harassment would be 3 and 110, respectively (combined, this annual take (n=113) which equates to approximately 0.19 percent of the stock abundance, if each take were considered to be of a different individual). Given the number of takes, while many of the takes likely represent exposures of different individuals on 1 day a year, some subset of the individuals exposed could be taken up to a few times annually.

Regarding the severity of takes by Level A harassment and Level B harassment, because harbor porpoises are particularly sensitive to noise, it is likely that a fair number of the responses could be of a moderate nature, particularly to foundation installation. In response to foundation installation, harbor porpoises are likely to avoid the area during construction, as previously demonstrated in Tougaard *et al.* (2009) in Denmark, in Dahne *et al.* (2013) in Germany, and in Vallejo *et al.* (2017) in the United Kingdom, although a study by Graham *et al.* (2019) may indicate that the avoidance distance could decrease over time. However, foundation installation is scheduled to occur off the coast of Massachusetts and given alternative foraging areas, any avoidance of the area by individuals is not likely to impact the reproduction or survival of any individuals.

With respect to PTS and TTS, the effects on an individual are likely relatively low, given the frequency bands of pile driving (most energy below 2 kHz) compared to harbor porpoise hearing (150 Hz to 160 kHz, peaking around 40 kHz). Specifically, TTS is unlikely to impact hearing ability in their more sensitive hearing ranges or the frequencies in which they communicate and echolocate. We expect any PTS that may occur to be within the very low end of their hearing range where harbor porpoises are not particularly sensitive and any PTS would be of small magnitude. As such, any PTS would not interfere with key foraging or reproductive strategies necessary for reproduction or survival.

As discussed in Hayes *et al.* (2022), harbor porpoises are seasonally distributed. During fall (October through November) and spring (April through June), harbor porpoises are widely dispersed from New Jersey to Maine with lower densities farther north and south. During winter (January to March), intermediate densities of harbor porpoises can be found in waters off New Jersey to North Carolina and lower densities are found in waters off New York to New Brunswick, Canada. In non-summer months they have been seen from the coastline to deep waters (>1800 m; Westgate *et al.,* 1998), although the majority are found over the continental shelf. While harbor porpoises are likely to avoid the area during any of the project's construction activities, as demonstrated during European wind farm construction, the time of year in which most work would occur is when harbor porpoises are not in highest abundance, and any work that does occur would not result in the species' abandonment of the waters off of Massachusetts.

Given the magnitude and severity of the impacts discussed above, and in consideration of the required mitigation and other information presented, the specified activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on the Gulf of Maine/Bay of Fundy stock of harbor porpoises.

Phocids (Harbor Seals and Gray Seals)

The harbor seal and gray seal are not listed under the ESA, and neither the western North Atlantic stock of gray seal nor the western North Atlantic stock of harbor seal are considered depleted or strategic under the MMPA. There are no known areas of specific biological importance in or around the LIA. As described in the Description of Marine Mammals in the Area of Specified Activities section, a UME has been designated for harbor seals and gray seals and is described further below. No serious injury or mortality is anticipated or proposed to be authorized for this species.

For the 2 seal species, the IHA would authorize up to between 30 (harbor seals) and 241 (gray seals) takes, by harassment only. The maximum allowable take for harbor seals by Level A harassment and Level B harassment would be 1 and 29, respectively (combined, this take (n=30) equates to approximately 0.05 percent of the stock abundance, if each take were considered to be of a different individual). No takes by Level A harassment are anticipated or proposed to be authorized for gray seals. The maximum allowable take for gray seals by Level B harassment (241) equates to approximately 0.88 percent of the stock abundance, if each take were considered to be of a different individual). Though gray seals and harbor seals are considered migratory and no specific feeding areas have been defined for the area, while some of the takes likely represent exposures of different individuals on 1 day a year, it is likely that some subset of the

individuals exposed could be taken a few times annually.

Harbor and gray seals occur in SNE waters most often from December through April. Seals are more likely to be close to shore, such that exposure to foundation installation would be expected to be at low levels. Known haulouts for seals occur along the shores of Massachusetts.

As described in the Potential Effects to Marine Mammals and Their Habitat section, construction of wind farms in Europe resulted in pinnipeds temporarily avoiding construction areas but returning within short time frames after construction was complete (Carroll *et al.,* 2010; Hamre *et al.,* 2011; Hastie *et al.,* 2015; Russell *et al.,* 2016; Brasseur *et al.,* 2012). Effects on pinnipeds that are taken by Level B harassment in the LIA would likely be limited to avoidance of the area reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals would simply move away from the sound source and be temporarily displaced from those areas (Lucke *et al.,* 2006; Edren *et al.,* 2010; Skeate *et al.,* 2012; Russell *et al.,* 2016). Given the low anticipated magnitude of impacts from any given exposure (*e.g.,* temporary avoidance), even repeated Level B harassment across a few days of some small subset of individuals, which could occur, is unlikely to result in impacts on the reproduction or survival of any individuals. Moreover, pinnipeds would benefit from the mitigation measures described in the Proposed Mitigation section.

As described above, noise from pile driving is mainly low frequency, and while any PTS and TTS that does occur would fall within the lower end of pinniped hearing ranges (50 Hz to 86 kHz), PTS and TTS would not occur at frequencies around 5 kHz where pinniped hearing is most susceptible to noise-induced hearing loss (Kastelein *et al.,* 2018). In summary, any PTS and TTS would be of small degree and not occur across the entire, or even most sensitive, hearing range. Hence, any impacts from PTS and TTS are likely to be of low severity and not interfere with behaviors critical to reproduction or survival.

Elevated numbers of harbor seal and gray seal mortalities were first observed in July 2018 and occurred across Maine, New Hampshire, and Massachusetts until 2020. Based on tests conducted so far, the main pathogen found in the seals belonging to that UME was phocine distemper virus, although additional testing to identify other factors that may be involved in this UME are underway. In 2022, a pinniped UME occurred in Maine with some harbor and gray seals testing positive for highly pathogenic avian influenza (HPAI) H5N1. Neither UME (alone or in combination) provides cause for concern regarding population-level impacts to any of these stocks. For harbor seals, the population abundance is over 61,000 and annual mortality/serious injury (M/SI) (n=339) is well below PBR (1,729) (Hayes *et al.,* 2023). The population abundance for gray seals in the United States is over 27,000, with an estimated overall abundance, including seals in Canada, of approximately 366,400 (Hayes *et al.,* 2023). In addition, the abundance of gray seals is likely increasing in the U.S. Atlantic, as well as in Canada (Hayes *et al.,* 2023).

Given the magnitude and severity of the impacts of the Vineyard Wind Project discussed above, and in consideration of the required mitigation and other information presented, Vineyard Wind's activities are not expected to result in impacts on the reproduction or survival of any individuals, much less affect annual rates of recruitment or survival. For these reasons, we have determined that the take by harassment anticipated and proposed to be authorized will have a negligible impact on harbor and gray seals.

Negligible Impact Determination

No mortality or serious injury is anticipated to occur or proposed to be authorized. As described in the analysis above, the impacts resulting from the project's activities cannot be reasonably expected to, and are not reasonably likely to, adversely affect any of the species or stocks through effects on annual rates of recruitment or survival. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and, taking into consideration the implementation of the proposed mitigation and monitoring measures, NMFS preliminarily finds that the marine mammal take from the proposed activities would have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only incidental take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

NMFS is authorizing incidental take by Level A harassment and/or Level B harassment of 14 species of marine mammals (with 14 managed stocks). The estimated number of instances of takes by combined Level A harassment and Level B harassment relative to the best available population abundance is less than one-third for all affected species and stocks. For 13 stocks, 1 percent or less of the stock abundance is proposed for take by harassment. Specific to the NARW, the estimated amount of take, which is by Level B harassment only (no Level A harassment is anticipated or authorized), is seven, or 2.07 percent of the stock abundance, assuming that each instance of take represents a different individual. Please see table 3 for information relating to this small numbers analysis.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of

IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with NOAA GARFO.

There are four marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA that may taken, by harassment, incidental to construction of the project: the North Atlantic right, sei, fin, and sperm whale. NMFS issued a Biological Opinion on September 11, 2020, concluding that the issuance of the 2023 Vineyard Wind IHA is not likely to jeopardize the continued existence of threatened and endangered species under NMFS' jurisdiction and is not likely to result in the destruction or adverse modification of designated or proposed critical habitat. The Biological Opinion is available at *https://repository.library.noaa.gov/view/noaa/37556.*

The Permit and Conservation Division requested re-initiation of section 7 consultation with GARFO on the issuance of the Vineyard Wind proposed IHA for Phase 2 of the Vineyard Wind Offshore Wind Project. NMFS will conclude the ESA consultation prior to reaching a determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Vineyard Wind for conducting impact pile driving of monopiles in the Vineyard Wind Offshore Wind Farm offshore of Massachusetts, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable.*

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed pile driving activities. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA.

Dated: April 15, 2024.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

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Vol. 89, No. 79

Tuesday, April 23, 2024

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FEDERAL REGISTER PAGES AND DATE, APRIL

22327–22606	1
22607–22878	2
22879–23496	3
23497–23906	4
23907–24336	5
24337–24680	8
24681–25116	9
25117–25496	10
25497–25748	11
25749–26102	12
26103–26754	15
26755–27354	16
27355–27650	17
27651–28568	18
28569–29246	19
29247–30256	22
30257–31064	23

CFR PARTS AFFECTED DURING APRIL

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

1	30046
25	30046
170	30046
175	30046
180	30046
182	30046
183	30046
184	30046
200	30046

3 CFR

Proclamations:

10714	22879
10715	22881
10716	22883
10717	22885
10718	22887
10719	22889
10720	22891
10721	22893
10722	22895
10723	22899
10724	22901
10725	23497
10726	25747
10727	26103
10728	30257

Executive Orders:

13910	27355
13991	27355
13998	27355
14121	22327
14122	27355

Administrative Orders:

Memorandums:	
Memorandum of March 26, 2024	24679
Notices:	
Notice of April 9, 2024	25493
Notice of April 9, 2024	25495
Notice of April 16, 2024	27649

5 CFR

210	24982
212	24982
213	24982
297	25749
300	25751
362	25751
410	25751
302	24982
432	24982
451	24982
752	24982
1201	24681

Proposed Rules:

532	25186

6 CFR

3	23499
Ch. I	28569, 28570

Proposed Rules:

226	23644

7 CFR

210	28572
220	28572
225	28572
246	28488
292	28572
301	23500
927	25775
987	25778
989	24337

Proposed Rules:

66	25187
930	28682
959	24393
1223	25543

8 CFR

103	22607
214	22903
235	22607
258	23501
274a	24628
1003	22630

9 CFR

93	24339
441	22331

10 CFR

30	22636
40	22636
50	22912
52	22912
70	22636
72	28572
430	22914, 24340, 25780, 28581, 28876
431	29834

Proposed Rules:

72	28687
429	24206
430	24206

11 CFR

Proposed Rules:

113	24738

12 CFR

628	25117
Ch. X	27357, 27361
1091	30259

Proposed Rules:

5	26106
303	29922

14 CFR

25	23504, 23507

39 .....22333, 22925, 22928, 22932, 24363, 24682, 24684, 24686, 24689, 24691, 26755, 27363, 27366, 27368, 27371, 27374, 27376, 27379, 27383, 27651, 29247
61.....22482, 29252
63.....22482, 29252
65.....22482, 29252
71 .....23510, 24366, 24367, 27652, 29253
97 .....22334, 22336, 24369, 24371
107.....23907
1204.....26757
1216.....25497

Proposed Rules:
39 .....22356, 22358, 22640, 23529, 23951, 24742, 24745, 24748, 25189, 25191, 25194, 25823, 25825, 26794, 27398, 29274, 30281, 30284, 30286, 30289
71 .....22362, 22642, 23532, 26796, 27691, 27695, 30292

15 CFR

732.....23876
734.....23876, 28594
736.....23876
738.....28594
740.....23876, 28594
742.....23876, 28594
743.....28594
744 .....23876, 25503, 28594
746.....23876, 29254
748.....23876
754.....28594
758.....23876, 28594
770.....23876
772.....23876, 28594
774.....23876, 28594

16 CFR

310.....26760
1700.....28604

Proposed Rules:
305.....22644
306.....27401
310.....26798
1112 .....27246, 30294, 30295
1130.....30294, 30295
1218.....27246
1242.....30294
1243.....30295

17 CFR

210.....25804
229.....24372, 25804
230.....25804
232 .....24372, 25804, 28606
239.....25804
240.....24372, 26428
242.....26428
249.....24372, 25804
274.....24372
275.....24693
279.....24693

18 CFR

35.....27006

Proposed Rules:
284.....23954

19 CFR

12.....25130

20 CFR

404.....27653
416 .....25507, 27653, 28608

21 CFR

1308.....25514, 25517

Proposed Rules:
1308.....24750, 25544

22 CFR

62.....30268
303.....25519

24 CFR

5.....30272
50.....30850
55.....30850
58.....30850
115.....22934
125.....22934
200.....30850
201.....26105
202.....30272

Proposed Rules:
5.....25332
245.....25332
882.....25332
960.....25332
966.....25332
982.....25332

26 CFR

1.....26786, 29257
54.....23338
301.....26786

Proposed Rules:
1 .....22971, 24396, 25550, 25551, 25980
53.....28690
54.....22971
58.....25829, 25980
301.....22971

27 CFR

9.....24378
478.....28622, 28968

28 CFR

106.....28633

29 CFR

102.....24713, 25805
1636.....29096
1903.....22558
2550.....23090
2590.....23338

Proposed Rules:
2510.....22971
2520.....22971
2550.....22971
4000.....22971
4007.....22971
4010.....22971
4041.....22971
4041A 22971
4043.....22971
4050.....22971
4062.....22971
4063.....22971
4204.....22971
4211.....22971
4219.....22971
4231.....22971
4245.....22971
4262.....22971
4281.....22971

30 CFR

56.....28218
57.....28218
60.....28218
70.....28218
71.....28218
72.....28218
75.....28218
90.....28218
723.....23908
724.....23908
733.....24714
842.....24714
845.....23908
846.....23908

31 CFR

33.....26218
525.....27668
541.....27386

Proposed Rules:
800.....26107
802.....26107

32 CFR

Proposed Rules:
246.....30296

33 CFR

1.....22942
5.....22942
100 .....25139, 25531, 25806, 25807, 27386, 27387
104.....22942
117.....24381, 24383
151.....22942
155.....22942
161.....22942
164.....22942
165 .....22637, 22942, 23512, 23911, 23914, 24385, 24387, 25140, 25808, 25810, 27388, 27389, 27669, 27670, 28638
174.....22942
175.....22942

Proposed Rules:
100.....28691
101.....24751
110.....25197, 30299
117.....24396, 25198
160.....24751
165 .....22645, 25553, 25835, 27401

34 CFR

Ch. VI.....23514

Proposed Rules:
30.....27564
682.....27564

36 CFR

242.....22949

37 CFR

Proposed Rules:
1.....23226
41.....23226
42 .....23226, 26807, 28693

38 CFR

17.....23518
36.....25142

Proposed Rules:
76.....24752

39 CFR

20.....27392

Proposed Rules:
20.....27403
111.....27330
3030.....25554

40 CFR

52 .....22337, 22963, 23521, 23523, 23526, 23916, 24389, 25810, 28640, 29257, 29259
60.....24090, 27392
63 .....23294, 23840, 24090
70.....28640
75.....23526
78.....23526
81.....25144
85.....27842
86.....27842, 29440
97.....23526
136.....27288
180.....25531, 30277
600.....27842
1036.....27842, 29440
1037.....27842, 29440
1039.....09440
1054.....09440
1065.....29440
1066.....27842
1068.....27842

Proposed Rules:
50.....26114, 26620
52 .....22363, 22648, 25200, 25216, 25223, 25555, 25838, 25841, 25849, 26115, 26813. 26817, 27697, 29277
63.....26835
131.....24758
721.....24398
751.....22972

41 CFR

102–3.....27673

Proposed Rules:
102–118.....24775

42 CFR

10.....28643
411.....25144
413.....25144
417.....30448
422.....30448
423.....30448
431.....22780
435.....22780
436.....22780
447.....22780
457.....22780
460.....30448
488.....25144
489.....25144
600.....22780, 26218

Proposed Rules:
412.....23146
413.....23424
418.....23778
488.....23424

43 CFR

2800.....25922
2860.....25922
2880.....25922
2920.....25922
3000.....30916
3100.....30916

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws/current.html*.

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S. 382/P.L. 118–48
Puyallup Tribe of Indians Land Into Trust Confirmation Act of 2023 (Apr. 19, 2024)
Last List March 26, 2024

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